# PATENT LAW AND NON-PROFIT RESEARCH COLLABORATION

### **HEARING**

BEFORE THE

SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY

OF THE

# COMMITTEE ON THE JUDICIARY HOUSE OF REPRESENTATIVES

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# PATENT LAW AND NON-PROFIT RESEARCH COLLABORATION

#### THURSDAY, MARCH 14, 2002

House of Representatives,
Subcommittee on Courts, the Internet,
AND INTELLECTUAL PROPERTY,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to call, at 9:03 a.m., in Room 2141, Rayburn House Office Building, Hon. Howard Coble [Chairman of the Subcommittee] presiding.

Mr. COBLE. Good morning, ladies and gentlemen. Welcome to the

hearing this morning.

And at the outset, I've already told Howard, I apologize for my raspy voice, but I have been plagued all week with a cold. At this juncture, it sounds worse than it is, but it sounds terrible. So you all bear with me.

All of us know the great inventors in history—Thomas Edison, for instance—and the advancements they made that have enriched our lives and changed the world. While there are the lone wolf inventors, the normal course of practice is that they do not normally work alone. The Wright brothers, Hewlett and Packard, and, in the biotechnology field, Cohen and Boyer, are but a few examples.

The reality is that the modern research environment is more dynamic than ever and more frequently requires teams of inventors

collaborating among research institutions.

There are many benefits arising from university research collaborations, including speeding breakthroughs to the public, providing crucial funding for education, and exposing students and faculty to advanced training and technology. The results are impressive for both the funding generated by these collaborations as well as the number of patented technological breakthroughs.

In addition, I cannot emphasize enough the benefit of university patents in an open society, since patents result in the publication of scientific and technical data for the world to study and build

upon.

The Subcommittee has been approached by the university community with serious concerns about an issue arising from a recent case interpreting the Patent Act. In the *OddzOn Products* case, the Court of Appeals for the Federal Circuit held that certain confidential material exchanged in the course of a research collaboration would defeat the patents later developed.

In fact, the *OddzOn* case attempts to resolve the situation as envisioned by Congress, but the literal reading of the statute is in conflict, it seems to me, with its apparent intent.

Further, the court explicitly notes that, in light of the result, the

Congress may later wish to intervene in this area.

It is appropriate for our Subcommittee to review this apparent quirk under section 103(c) of the Patent Act, Title 35 U.S. Code, which recites the requirement of non-obviousness.

In 1984, Congress amended section 103(c) with the hope of improving the environment for nonprofit collaboration and joint team

research.

Critics argue that in *OddzOn*, the Federal Court read the provisions of section 103(c) far too narrowly, defeating the intent of Congress in passing the 1984 amendments. While many across the patent community acknowledge a legislative remedy is required in light of the apparent jeopardy, there is disagreement about its form.

Perhaps and hopefully our witnesses will make some suggestions

to us today about any legislative proposals they envision.

We are indeed privileged to have a distinguished panel of witnesses to help shed some light upon this complicated area of the law and to improve the patent system and the research across the nonprofit world.

[The prepared statement of Mr. Coble follows:]

PREPARED STATEMENT OF THE HONORABLE HOWARD COBLE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Good Morning. The Subcommittee will come to order.
All of us know of the great inventors in history, for instance Thomas Edison, and the advancements they made that have enriched our lives and changed the world. While there are the lone wolf inventors, the normal course of practice is that they do not work alone. The Wright Brothers, Hewlett and Packard, and in the biotechnology field, Cohen and Boyer, are but a few examples. The reality is that the medium research environment is more dynamic than even and more frequently remodern research environment is more dynamic than ever, and more frequently requires teams of inventors collaborating among research institutions.

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It is appropriate for our Subcommittee to review this apparent quirk under section 103(c) of the Patent Act (Title 35 United States Code), which recites the requirement of "non-obviousness." In 1984, Congress amended section 103(c) with the hope of improving the environment for non-profit collaboration and joint team re-

search.

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<sup>&</sup>lt;sup>1</sup>Oddzon Products, Inc. v. Just Toys, Inc. ,122 F.3d 1396 (Fed. Cir 1997).

is required in light of the apparent jeopardy, there is disagreement about its form. Perhaps our witnesses will make some suggestions about any legislative proposals they envision.

We are privileged to have a distinguished panel of witnesses to help us shed some light on this complicated area of the law to improve the patent system and the re-

search across the non-profit world.

I now turn to the Ranking Member for his statement.

Mr. COBLE. I am now pleased to recognize my good friend, the Ranking Member from California, Howard Berman.

Mr. BERMAN. Thank you very much, Mr. Chairman. Thank you for calling this hearing on the impact of patent law on joint research.

And I want to thank our witnesses for coming today.

Our panel represents a range of university representatives and experts in the patent community, and I look forward to hearing their perspectives on the intersection of patent law and collaborative research.

As legislators, we have a long history of fostering research collaborations and stimulating the transfer of information and tech-

nology from the research environment to the marketplace.

The Bayh-Dole Act of 1980 promotes technology transfer relationships among universities, nonprofit institutions, and private companies. These collaborations result in an estimated \$40 billion of economic activity each year, and support some 270,000 jobs. The Stevenson-Wydler Technology Innovation Act encourages collaborations between Federal laboratories and other entities; an estimated 500 such research agreements have been signed since 1986.

There is no question that research collaborations are a key element to the success of the U.S. economy. The question before us today is how we can continue to provide an environment in which researchers have the freedom and opportunity to develop inven-

tions and new ideas.

Specifically, I hope to learn at today's hearing what we can do to prevent information that is shared among research collaborators at nonprofit institutions from invalidating a patent application.

The decision that Chairman Coble referred to established that information qualifying as prior art under subsections 102(f) or 102(g) of Title 35 can be used to dismiss a patent application as obvious under subsection 103(c) of Title 35.

That dismissal can occur even if that information was confidential, shared among consenting parties, or undocumented.

An otherwise patentable invention can be denied a patent simply because research partners have exchanged information. This can

cause a chilling effect on collaborative research.

What makes this particularly troubling is that this affects research universities and nonprofit institutions much more than it does private companies. There are ways to maneuver around the threat of 103(c)—by creating a joint venture, or by assigning intellectual property rights to a single entity. However, many State and Federal Government organizations simply can't assign rights to an outside partner due to their established laws and practices. Public research institutions may not have the means to circumvent the potential problems of 103(c).

When we amended the statute in 1984, we were careful to allow for the disclosure of information among collaborators within the same organization. But the original intent of section 103(c) was to promote teamwork and to stimulate collaborative work. In 1984, the research paradigm was one in which collaborations across institutions was a rarity. Thus, we apparently just neglected to include this possibility in the language of section 103(c). Probably our only mistake. [Laughter.]

It may be time to correct this oversight, and I am interested to hear the opinions of our witnesses on these issues. Thank you, Mr.

Chairman.

[The prepared statement of Mr. Berman follows:]

PREPARED STATEMENT OF THE HONORABLE HOWARD L. BERMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

I thank you for calling this hearing on the impact of patent law on joint research. I also wish to thank our four witnesses for appearing here today. Our panel represents a range of university representatives and experts in the patent community, and I look forward to hearing their perspectives on the intersection of patent law and collaborative research.

As legislators, we have a long history of fostering research collaborations and stimulating the transfer of information and technology from the research environment to the marketplace. The Bayh-Dole Act of 1980 promotes technology transfer relationships among universities, non-profit institutions, and private companies. These collaborations result in an estimated \$40 billion of economic activity each year, and support some 270,000 jobs. The Stevenson-Wydler Technology Innovation Act encourages collaborations between Federal laboratories and other entities—an estimated 5000 such research agreements have been signed since 1986.

There is no question that research collaborations are a key element to the success of the U.S. economy. The question before us today is how we can continue to provide an environment in which researchers have the freedom and opportunity to develop inventions and new ideas. Specifically, I hope to learn at today's hearing what we can do to prevent information that is shared among research collaborators at non-

profit institutions from invalidating a patent application.

A decision by the Federal Circuit court in 1997 showed us that information qualifying as prior art under subsections 102(f) or 102(g) of Title 35 can be used to dismiss a patent application as obvious under subsection 103(c) of Title 35. This dismissal can occur even if that information was confidential, shared among consenting parties, or undocumented. An otherwise patentable invention can be denied a patent simply because research partners have exchanged information. This, undoubtedly, can cause a chilling effect on collaborative research.

What makes this particularly troubling is that this affects research universities and non-profit institutions much more than it does private companies. There are ways to maneuver around the threat of 103(c)—by creating a joint venture, or by assigning intellectual property rights to a single entity. However, many state and federal government organizations cannot assign rights to an outside partner due to their established laws and practices. Public research institutions may not have the

means to circumvent the potential problems of 103(c).

When we amended the statute in 1984, we were careful to allow for the disclosure of information among collaborators within the same organization. The original intent of Section 103(c) was to promote teamwork and to stimulate collaborative work. In 1984, the research paradigm was one in which collaborations across institutions was a rarity. Thus, we apparently just neglected to include this possibility in the language of Section 103(c). It may be time to correct this oversight, and I am interested to hear the opinions of our witnesses on this issue.

Mr. Coble. Thank you, Howard.

The distinguished gentleman from Texas, who chairs the Crime Subcommittee of the full Judiciary Committee, has requested permission to sit in on this hearing today, and I ask unanimous consent that Lamar Smith be allowed to join us.

Mr. Berman. I heartily approve.

Mr. SMITH. Mr. Chairman, may I thank you for allowing me to sit in on the hearing. As I mentioned, there are three universities that are located in counties I represent: the University of Texas, Southwest Texas State, and Trinity University, all of which have a special interest in the subject at hand. So I thank you for the courtesies you're extending.

Mr. Coble. Good to have you.

And I will recognize the gentlelady and distinguished lady from Wisconsin subsequently, when we come to her constituent, who is one of our witnesses.

You all bear with me. I'm going to give a fairly extended introduction, because I think it's important that people in the audience and the staffers, in case they don't know the credentials of our witnesses. I think this is important. We have a very prestigious panel this morning.

And, Howard, I think you'll agree, we've been blessed with prestigious panels generally.

We've had outstanding witnesses to appear before our Subcommittee. Today is no exception.

We are pleased to have four distinguished members of the bar with us this morning.

Our first witness is not only an attorney with expertise in the patent field, the recipient of 15 patents, but he is also a best-selling author. Mr. Kevin Rivette is co-author of "Rembrandts in the Attic," which describes the strategic use of patents in research within an organization.

He travels the world extolling the benefits that lay within the intellectual property system, with a focus on the successful use of patent strategies for competitive advantage in research and development.

In addition to his work and leadership in the field of intellectual property and asset management, he practices what he preaches. Mr. Rivette is a former patent attorney and has previously served as president of several high-tech and investment-related firms. He has founded several businesses from scratch and is a co-founder of the Aurigin Systems.

He earned a B.S. from the University of Kansas School of Business in 1979 and a J.D. from the University of Santa Clara.

Our second witness is equally distinguished and is a constituent of the gentlelady from Wisconsin. I am now pleased to recognize Ms. Baldwin for his introduction.

Ms. BALDWIN. Thank you, Mr. Chairman.

It is my honor to introduce our second witness, Dr. Carl Gulbrandsen, who is one of my constituents, as mentioned.

Dr. Gulbrandsen is from the Wisconsin Alumni Research Foundation, commonly known as WARF. He is testifying on behalf of the Council on Government Relations also.

Dr. Gulbrandsen received his B.A. from St. Olaf's College in Northfield, Minnesota, and his Ph.D. in physiology from the University of Wisconsin Madison campus, and a J.D. degree from the University of Wisconsin Law School.

In 1992, Dr. Gulbrandsen joined Madison, Wisconsin, companies Lunar Corporation, a medical device company, and Bone Care International, a pharmaceutical company, as general counsel.

Mr. Gulbrandsen joined the Wisconsin Alumni Research Foundation, WARF, in October 1997, as director of patents and licensing. And January 1st, 2002, he became the managing director.

He is admitted to practice in Wisconsin and the United States

Patent and Trademark Office.

From 1981 until 1992, he was in the private practice of law. Mr. Gulbrandsen's law practice concentrated in intellectual property

with a specialty in patent prosecution litigation.

He's a member of the Association of University Technology Managers, the Licensing Executive Society, and the American Intellectual Property Law Association, the Wisconsin State Bar, and the American Bar Association.

Welcome to our Subcommittee, Dr. Gulbrandsen. Thank you for being here.

Mr. Coble. Thank you, Tammy. I appreciate that.

Our third witness is Mr. Charlie Van Horn, who is testifying on behalf of the American Intellectual Property Law Association, AIPLA, as we know you.

Mr. Van Horn is a partner in the law firm of Finnegan, Hender-

son, Farabow, Garrett & Dunner LLP, based here in D.C.

Prior to private practice, Mr. Van Horn served 31 years in the U.S. Patent and Trademark Office. During his tenure, he served in a variety of leadership positions relating to patent policy and practice, including serving as the deputy solicitor and as the deputy assistant commissioner.

He was recipient of the Jefferson Medal in 2001 and received the

Department of Commerce Gold Medal in 1983.

Mr. Van Horn received his B.S. in chemical engineering from Lehigh University, his master's in business administration from the George Washington University, and his law degree from Washington College of Law at American University.

He is a member of the D.C. and Virginia bars.

Our fourth and final witness is Mr. Jon Grossman, an attorney and partner in the D.C. office of the firm Dickstein, Shapiro, Morin & Oshinsky LLP. He practices in the area of computer law with a focus on intellectual property issues, including the licensing and acquisition of software rights, with a background in patents, copyrights and trade secrets.

In the course of his practice, he represents several private and Land Grant academic institutions, including Johns Hopkins, the University of Maryland, and the University of Rochester.

Prior to private practice, Mr. Grossman was an examiner at the PTO, U.S. Patent and Trademark Office.

Mr. Grossman is a member of the Pennsylvania and District of Columbia bars, and is registered to practice before the U.S. Patent and Trademark Office.

Mr. Grossman is an adjunct professor as Johns Hopkins University, where he has taught for several years of high-technology law.

We are pleased to have been joined by the distinguished gentleman from Tennessee, Mr. Jenkins.

Mr. Jenkins, do you have a statement to make?

Mr. JENKINS. I do not, Mr. Chairman.

Mr. Coble. Good to have you with us. Good to have all of you with us.

Gentlemen, as you all have previously been beneficiaries of a request or, some call it, a direction, if you could confine your oral testimony to the 5-minute rule, we would be appreciative. Oftentimes, we're called to go hither and yon.

And we have read your written statements, and they will be ex-

amined again.

When you see the red light illuminate in your eyes, you will know that time is elapsing quickly.

Mr. Rivette, why don't you start us off? Strike that.

And if time permits, Howard, I think we may have a second round, if time permits, because that's in order, a second round of questions.

Mr. Rivette, you're on. Pull that mike a little closer to you and turn that on.

# STATEMENT OF KEVIN RIVETTE, ESQ., ATTORNEY AND AUTHOR

Mr. RIVETTE. Mr. Chairman, thank you for the opportunity to testify before you Subcommittee. I thank all the other Members.

You've read my remarks, I take it. I will go through some of

them; I will be open for questions.

To preface the remarks, one of the things that I wanted to make clear today was that I come from a perspective of private enterprise, and I wanted the Committee to understand that this collaboration relationship is critical to both the nonprofit and the private side of enterprise. Without it, we will have problems. Without it, it will slow down, in my opinion, the progression of new discoveries into productization, into useful things that all of us—medical devices, medicines, technology—all of us use.

As has been mentioned, this relationship has a long history and

As has been mentioned, this relationship has a long history and a good history. One of the things that I'd like to point out, though, is that it's also being copied around the world. In the remarks that Commissioner Isayama made in 1998 at the IPO annual convention, he specifically referenced the collaboration or cooperation, shall I say, among industry, Government, and academia as a key element in why the United States leads in most of the world's important technologies and the strength of our economy.

He went on to discuss how Japan was changing its patent laws, and I believe they have changed them significantly, to emulate this type of research between nonprofit and private organizations.

This is also occurring in Europe. One of the nonprofit institutes that I think we've seen profit by this is the Max Planck Society that specifically takes in research that no one else with touch, typically even universities won't go near it. I look at this somewhat as the Battelle institute and other institutes that we have here in the United States.

So I don't believe that these rules that we're looking at today only apply to universities. I think they apply across-the-board to nonprofits also.

In the case of the Max Planck Society in Europe, they have, in the course of about 20 years, produced about 179 deutschmarks from those research—from that research into licensing.

And I think the critical point here is that without the patent, the license will be very, very difficult for private industry to accept.

Private industry needs those license rights. Without the ability to protect it, it was a very interesting exercise, but it may not be one that's going to generate the kind of productization or the kind of return for the nonprofit organization that is necessary to help it continue and to help fund it.

The examples that I cited in my statement are well-known. The collaboration has generated companies such as Lycos, Google, Amati Semiconductors that was sold for over \$400 million dollars.

The products that these types of collaboration have helped is artificial lung surfactant, cancer therapeutics, diagnosis for heart disease, hepatitis B vaccines, cancer drugs like Taxol, Retina-A-I at least have most of my hair, but it seems to be coming out a little faster lately. [Laughter.]

They also have produced things like Cybercard from the Univer-

sity of Florida, and Smart Cards.

In my experience at Aurigin, we have also benefited from this type of collaboration. We needed a specific type of technology to actually represent large amounts of textual data. In our case, we were using the text of Worldwide Patents. There are over seven terabytes of this. We needed to have technology that would represent this in a way that was easy to understand.

And we found that in a product that actually had been started at the Battelle Memorial Institute, and we were the recipient of that type of that research. And that product today continues.

I applaud the Subcommittee for looking at these issues today. I think they are highly critical to continuing the progress of our economy, and the free flow of technology from the research institutes into the society at large. I believe that the legislation that we're going to talk about to further clarify the issues of the *OddzOn* case is necessary. And I'll take any questions.

[The prepared statement of Mr. Rivette follows:]

#### PREPARED STATEMENT OF KEVIN RIVETTE

Mr. Chairman, thank you for the opportunity to testify before your Subcommittee on the important topic of "patent law and non-profit research collaboration."

Before I make my remarks, I would like to take care of some disclosure issues. I am making these remarks at this hearing as a private citizen and not as part of or on behalf of any organization. I have not received and funds, grants, contract or subcontract from any Federal agency or program of any kind that would have any

relevancy to these hearings or my testimony.

My name is Kevin G. Rivette. I am the author of Rembrandts in the Attic, Unlocking the Hidden Value of Patents, co-founder of Aurigin Systems Inc. and a patent attorney. I have been involved with patents for most of my career. As a patent attorney I have written, licensed and litigated patents. As an inventor I have applied for and received them. As a business person I have raised money based on approximately 15 patents. I wrote Rembrandts in the Attic to help businesses develop effective strategies using patent information. I founded Aurigin Systems to develop the tools necessary to implement the ideas discussed in Rembrandts. Aurigin's products provide a way for patent and non-patent professionals to visualize and mine the rich research resources of the world's patent databases. It is my belief that the Non-profit/Private collaboration that has been enhanced by our patent laws is a critical driver in a vibrant economy. As I will discuss later in my remarks, Aurigin, its customers and its employees all benefited as a result of this special research collaboration between Non-profits and the private sector that we are discussing here today. Therefore, I am firmly in favor of legislation that enhances this Non-profit/Private industry research relationship.

#### I. COLLABORATIVE RESEARCH—THE BACKBONE OF AN INNOVATIVE SOCIETY

We live in one of the most innovative moments in history. Advances are coming faster today than ever before in all industries, such as medicine, aviation, computers, telecommunications. These advances and products come from two major sources, private industry labs and Non-profit organizations. In many cases the original research which might be too speculative for industry, is done at universities and research institutes. This original research needs to be further developed and productized to be beneficial to all of us. To do this additional development, industry and the Non-profit research organizations have developed an excellent feedback loop that provides industry with the needed research and the Non-profits with the needed funds to continue with further discovery. At the base of this feedback loop are patents. Patents are the mechanism that makes this collaboration work. It is the non-profit's ability to license these protected research results to industry for royalties, which permits free flow of discoveries to the public as new products. I suggest that this mechanism is one of the cornerstones of our economy today.

The importance of this protection is recognized worldwide. In a speech before the Intellectual Property Owners (IPO) annual meeting on November 16, 1998, then Japanese Patent Office Commissioner Takeshi Isayama attributed the "... cooperation among industry, government and academia" as a key element in why the US leads in most of the important world's important technologies and the strength of our economy. Commissioner Isayama went on to discuss how Japan was changing its patent laws to emulate this type of research collaboration between its

Non-profit and private organizations.

In Europe, this special research collaboration is currently working to further fundamental research and productization also. An example is the independent non-profit Max Planck Society for the Advancement of the Sciences. The Max Planck Society specifically looks to fund promising research that is not easily or readily undertaken by universities. This research is then patented and licensed to private industry. In the case of the Max Planck Society this research has enhanced the fields of chemistry, biotechnology, pharmacology, medical technology, solid-state physics and the manufacture of new materials. The royalties from products that industry has developed using these patents have, according to the Society, generated over DM 179m from 1979 to 1998. The Society then uses these royalties to continue funding other promising research. This type of symbiotic relationship benefits everyone with new products, medical cures, jobs and increased economic activity.

#### II. COLLABORATIVE RESEARCH—JOBS, WEALTH, AND MORE

Here in the United States the examples of the benefits of this type of collaboration are well documented and highly visible. Companies such as Lycos®, Google®, Amati Semiconductor and others have used this type of research to create jobs and billions of dollars of wealth. A 1/13/99 MIT article even states that, "University research is increasing and generates approximately \$29 billion of economic activity and 246,000 jobs through the commercialization of discoveries, the Association of University Technology Managers (AUTM) estimates in its seventh annual Licensing Survey."

In addition, that article lists a small sample of successful products and life saving drugs that have resulted from this Non-profit research collaboration. These products include:

- Artificial lung surfactant for use with newborns, University of California;
- Cisplatin and carboplatin cancer therapeutics, Michigan State University;
- Citracal® calcium supplement, University of Texas Southwestern Medical Center;
- Creatine-kinase antibody used in diagnosing heart disease, Washington University;
- Haemophilus B conjugate vaccine, University of Rochester;
- Hepatitis B vaccine, University of California and University of Washington;
- Human growth hormone (genetically engineered), City of Hope Medical Center;
- Leustatin® chemotherapy for hairy cell leukemia, Brigham Young University;
- · Metal alkoxide process for taxol production, Florida State University;
- Neupogen® used in conjunction with chemotherapy, Memorial Sloan Kettering Cancer Institute;
- Osteomark® osteoporosis diagnostic, University of Washington;
- Prostate-specific antigen test, HRI/Roswell Park Cancer Institute;

- DNA technology, central to biotechnology industry, Stanford and the University of California;
- Recombinant engineering co-transformation process, Columbia;
- Retin-A, University of Pennsylvania;
- Synthetic penicillin, MIT;
- TRUSOPT® (dorzolamide) ophthalmic drop used for glaucoma, University of Florida; and
- · Vitamin D, University of Wisconsin.

My experience is similar. Aurigin Systems Inc. was also a beneficiary of this collaboration. At Aurigin we created patent tools for business. These tools needed to visually represent huge amounts of unstructured patent and non-patent text in a way that could be easily understood by patent and non-patent professionals. In addition, this representation needed the ability to be further deconstructed to give the user perspective of the "landscape" they were interested in understanding. Aurigin needed something new, something that really improved the way people used large text results

Aurigin found a 3D topographical mapping product that was based on original research done by the Battelle Memorial Institute, a Non-profit institute for the development of basic research. Aurigin acquired the product and today companies such as GE, Dow, Dupont, Pfizer and others are using this technology to direct R&D projects, decide on Mergers and Acquisitions candidates and understand how their companies fit into the technology landscape. This was made possible in large part by basic research done by a Non-profit institute.

#### III. CONCLUSION

I applaud this subcommittee for looking at the issues before it today. I believe that legislation that furthers this special Non-profit research collaboration with private industry is in the best interest of our country and all people as we create new companies, jobs, and wealth, as well as helping to cure sickness and improve people's lives with products they want and need.

If there are any questions, I will be pleased to try to answer them.

Mr. COBLE. Thank you, Mr. Rivette.

Dr. Gulbrandsen?

# STATEMENT OF CARL GULBRANDSEN, PH.D., WISCONSIN ALUMNI RESEARCH FOUNDATION AND THE COUNCIL ON GOVERNMENT RELATIONS

Mr. GULBRANDSEN. I'd like first to thank Representative Baldwin for a kind introduction, and certainly thank Chairman Coble for his strong and very important leadership of this Committee.

Mr. Chairman, thank you for the opportunity to testify before your Subcommittee on the important topic of patent law and nonprofit research collaboration.

My name is Carl Gulbrandsen. I am the managing director of the Wisconsin Alumni Research Foundation, which we affectionately refer to as WARF. WARF is the patent management organization for the University of Wisconsin-Madison.

My statement today is also being made on behalf the Council on Governmental Relations, known as COGR. COGR is an association of 145 research-intensive universities in the United States.

WARF was founded in 1925 and is one of the earliest organizations engaged in university technology transfer. WARF exists to support scientific research at the University of Wisconsin. This mission is carried out by transferring university technology to the marketplace for the benefit of the university, the inventors, and the public. Licensing income is returned to the university to fund further scientific research.

Since its inception, WARF has returned over \$600 million to the university to fund further research.

There is no doubt that the United States is preeminent in the areas of high-technology. Our economic strength is in large part due to the relationship of our universities and U.S. industry in the

high-technology areas.

Some of the major reasons for this preeminence are, one, the funding by the Federal Government of basic research at our colleges and universities; two, the enormously successful policies of the Bayh-Dole Act, which established a uniform patent policy for federally funded inventions and requires a commercialization of those inventions—this act is in large part responsible for the vibrant technology transfer activities of all our major research universities, including the University of Wisconsin-Madison; and, three, the encouragement of collaborative research within universities and within the private sector by section 103(c) of the patent law, an amendment that this Committee was instrumental in enacting.

Economic stimulus of federally funded inventions is quantifiable. In 2000, for example, sales from products developed from inventions that were transferred from university research centers resulted in revenues of about \$42 billion.

The importance of collaborative research today is unquestionable and necessary because of the expense and complexity of research.

This is particularly true in high-technology and biotechnology. The cross-disciplinary nature of those technologies mandate collaborative research.

At Wisconsin, for example, we've moved to cross-disciplinary hiring to encourage such collaborations. WARF itself has over 70 inter-institutional agreements with other universities and with industries. Many of these agreements anticipate jointly owned inventions arising out of collaborative research projects.

This is crucial in areas of medical research, such as medical imaging areas and biotechnology. These agreements also contemplate

jointly owned inventions.

In spite of the trend toward scientific collaboration, and the economic and practical necessity for such collaborations, a recent decision of the U.S. Court of Appeals for the Federal Circuit threatens to chill such collaborative activity. This decision, which cries for correction, is *OddzOn Products Inc.* v. *Just Toys Inc.* That holding makes it clear that information under section 102 could be used to invalidate a patent in circumstances of joint collaborative research where there is joint ownership of the invention.

This is clearly not what Congress and this Subcommittee intended when it amended section 103(c) in 1984 in order to encourage open communications among members of research teams working in corporations, universities, and organizations. The legislative history of the 1984 amendment clearly establishes that section

103(c) was broader than teamwork within organizations.

Changing section 103(c) will be of material benefit to universities and to corporate research labs where free exchange of ideas may have been hampered by the current state of the law with respect to what constitutes prior art. Effectively, the *OddzOn* decision cre-

ates a significant threat for the loss of intellectual property rights

for inventors that engage in joint research projects.

The solution is a legislative one. The OddzOn court itself invited Congress to review its decision, stating "it is sometimes more important that a close question be settled one way or another than which way it is settled. We settled the issue," the court said, "sub-

ject, of course, to any intervention by Congress.

Toward that end, we would propose a clarifying amendment to section 103(c) that would result in increasing the flow of information among scientists at different institutions, increase the collaboration of scientists both within and without an institution, promoting collaborations between the university and private sector, promoting collaborations between Government laboratories and the private sector as well as the university sector, and enhancing the national pool of knowledge because of the great unhindered flow of information among scientists.

Mr. Chairman, thank you again for your time and attention. In conclusion, I leave you with these recommendations: An amendment to the Patent Act is necessary to promote collaborative research amongst university and the nonprofit sector, the private sector, and the Government to achieve the promise of the 1984 amendments. This amendment will, prospectively, reverse the holding of

*OddzOn* decision. Thank you.

[The prepared statement of Mr. Gulbrandsen follows:]

#### PREPARED STATEMENT OF CARL E. GULBRANDSEN

Mr. Chairman, thank you for the opportunity to testify before your Subcommittee

Mr. Chairman, thank you for the opportunity to testify before your Subcommittee on the important topic of "patent law and non-profit research collaboration."

My name is Carl E. Gulbrandsen. I am the Managing Director of the Wisconsin Alumni Research Foundation, known as WARF. WARF is the patent management organization for the University of Wisconsin-Madison. My statement today is being made on behalf of WARF and the Council on Governmental Relations known as COGR. COGR is an association of 145 research-intensive universities in the United States. They promote policies and practices in research administration that balance accountability and recognition of the interests of all parties in achieving the maximum scientific benefit from both federal and institutional investments in research. Neither WARF nor COGR have received any federal grants, or engaged in any federal contracts or subcontracts that require reporting under House rules.

#### I. BACKGROUND

WARF was founded in 1925 and is one of the earliest organizations engaged in university technology transfer. WARF exists to support scientific research at the University of Wisconsin-Madison. This mission is carried out by transferring university technology to the marketplace for the benefit of the university, the inventors and the public. Licensing income is returned to the university to fund further scientific research.

Over its 76-year existence, WARF has contributed over \$600 million of licensing income to UW-Madison scientific research; but of greater significance is the fact that WARF's technology transfer successes have had a profound and positive effect upon the welfare, health and safety of humankind. Included among university inventions patented and licensed by WARF are: Professor Harry Steenbock's Vitamin-D invention which essentially eradicated rickets as a childhood disease; Professor Karl Elvehjem's copper-iron complexes which improved the physiological assimilation of iron in humans; Professor Karl-Paul Link's discovery of Coumadin(r), the most widely used blood-thinner for treatment of cardiovascular disease, and its counterpart Warfarin, still the most widely used rodenticide world-wide; Professor Charles Mistretta's digital vascular imaging technology which enabled accurate diagnosis of blockage of the vessels of the heart; Professor Hector DeLuca's Vitamin-D derivatives which are widely used to treat osteoporosis, renal disease and other diseases; and currently, Professor James Thompson's human embryonic stem cell lines which have unprecedented potential for research and clinical application of presently untreatable diseases such as Parkinson's disease and diabetes. In total, the benefit to the public derived from these and other inventions is incalculable.

The success of bringing these and countless university inventions to the marketplace has depended on rich collaborations among scientists within the university; collaborations among scientists at different universities and collaborations among university and industry scientists. Collaboration among scientists in husbanding research dollars makes good sense with the cost and complexity of research today especially with various institutions engaged in essentially the same technological areas. Moreover, the evolution of science has made interdisciplinary research more and more common and, in fact essential, if solutions to complex problems are to be found. A very recent stunning example of this is the sequencing of the human ge-

Collaborative research among, private, public and non-profit entities is quantifiably important to the U.S. economy. In 2000, non-profits and universities spent a record \$28.1 billion on research and development much of which involved collaborations among private, public and non-profit entities. The positive effects of these collaborations on the U.S. economy are substantial. For example, in 2000, sales from products developed from inventions that were transferred from university research centers resulted in revenues of about \$42 billion,¹ and U.S. universities, hospitals and research institutes realized almost \$1.2 billion in gross license income much of which was used to fund additional research.²

Public funding of university research and the encouragement of collaborations among scientists at public, private and non-profit entities has been a keystone of the United States strength and leadership in high technology and biotechnology. With the bulk of university research being supported through federal grants and contracts, to be prudent with the taxpayer's money, it again makes good policy sense to encourage collaboration among scientists for the public interest. And actually, there has been an increase in the public of collaboration. there has been an increase in the number of collaborations. Today WARF has over 70 inter-institutional agreements reflecting such collaborations. In these inter-institutional agreements, there is joint ownership of the results of the research by the collaborating scientists since most institutional agreements. collaborating scientists since most institutions operate under the provisions of law that give the institution the right to retain title to any invention made with federal funds. That is the applicable rule even where the institution is in a sub-contracting situation where the prime contractor is the recipient of federal funds. Thus, in collaboration on an invention, each party may hold ownership rights.

#### II. UNIVERSITY PATENT LICENSING

University patent licensing as we know it today has its roots in enactment in 1980 of Pub. L. No. 96–517, the Patent and Trademark Law Amendments Act, and amendments included in Pub. L. No. 98-628, enacted into law in 1984. See 35 U.S.C. §§ 200-212. This Subcommittee played an instrumental role in the crafting of a chapter of the Patent Act relating to patent rights in inventions made with federal assistance (chapter 18) (referred to as the Bayh-Dole Act), and its cardinal principle that the public benefits from a policy that permits universities and small businesses to elect ownership of inventions made under federal funding and to become participants in the commercialization process. After 1984, universities and colleges developed and strengthened the internal expertise needed to engage effectively in the patenting and licensing of inventions. A measure of the success of Bayh-Dole Act is the growth of the Association of University Technology Managers ("AUTM") from 113 members in 1979 to over 1800 today. The Act, so successful in the transfer of university technology to industry, encourages collaborations between industry and university scientists. It is well known that industry depends heavily on collaborations with universities for basic research. In the pharmaceutical, biotech and hitechnology areas, America's universities are the engines of cutting-edge ideas that have kept this country's industries the world leader in new technology. These collaborations between scientists at separate universities and between industrial and university scientists often result in joint inventions.

#### III. A THREAT TO COLLABORATIVE RESEARCH

In spite of the trend toward scientific collaboration and the economic and practical necessity for such collaborations, a recent decision of the U.S. Court of Appeals for the Federal Circuit threatens to chill such collaborative activity. This decision,

<sup>&</sup>lt;sup>1</sup>Calculated on the realized gross license income applying an average of 3% as the royalty

charge.

<sup>2</sup> Citing AUTM Licensing Survey 2000, Association of University Technology Managers, Inc.,

which cries for correction, is Oddzon Products, Inc. v. Just Toys, Inc.3. Oddzon interpreted subsection 103(c) of the Patent Act to hold that prior art under subsections 102 (f) and (g)4 could be used to determine the obviousness of an invention where:

- there was no common ownership or assignment of the invention and information being shared among collaborators; and
- b. the information exchanged was not publicly known.

That holding made it clear that information under 102 (f) or (g) could invalidate a patent in the circumstances of joint collaborative research. The Oddzon decision has been viewed as creating a significant threat for the loss of intellectual property rights for inventors who engage in joint research and development projects with scientists not employed by the same entity, be it a university or corporation. Thus, while the need for collaborative research in the public interest is becoming more and more evident, the Oddzon decision exerts a substantial chilling effect on collaborative efforts among universities, the private sector and the government

This is clearly not what Congress, and this Subcommittee, intended when it amended section 103(c) in 1984 in the Patent Law Amendments Act of 1984<sup>5</sup> in order to encourage open communication among members of research teams working in corporations, universities or other organizations. See Remarks of Robert W. Kastenmeier, 129 Cong. Rec. E5777 (daily ed., Nov. 18, 1983). It was considered at that time important to the economic interests of our country to encourage collaborative research. This provision of the patent law was particularly important for large corporations that rely on open communication and collaboration among various research teams within the corporation and has succeeded in encouraging free communication among the employees of large corporations and within universities.

A bit of legislative and judicial background is in order. The current quandary regarding section 103 had its roots in a decision of the caselaw of the U.S. Court of Customs and Patent Appeals, the forerunner of the Federal Circuit, which interpreted section 103 to mean that earlier inventions made by individual members of a research team would be used under section 103 to preclude the team's invention from being patented. This caselaw was a significant concern to entities, both public and private, that utilize team research. Seeking reform, they approached this Subcommittee. And the Subcommittee responded, producing a legislative proposal that was enacted into law. See P.L. No. 98–622, 98th Cong., 2d Sess. (1984), 98 Stat. 3383. Section 103 was amended by adding the current subsection 103(c) to address the problem created by the CCPA's interpretation related to team research within an organization. The legislative history of the 1984 amendment clearly establishes that subsection 103(c) was designed to help encourage teamwork at least within organizations. Given the text of subsection 103(c) and its legislative history, it is clear that the enactment of subsection 103(c) sought to encourage teamwork among researchers, rather than stifle team research. In floor debate, Rep. Kastenmeier (who served as floor manager) characterized the amendment as being broader than teamwork "within" organizations, stating that the "change will be of material benefit to university and corporate research laboratories where the free exchange of ideas and concepts may have been hampered by the current state of the law with respect to what constitutes 'prior art.'" See 130 Cong. Rec. H10522, 10529 (daily ed., Oct. 1, 1984), section-by-section analysis inserted in the record by Rep. Kastenmeier. Thus, it can safely be assumed that certain inter-organizational exchanges were not expressly exempted because there was a different research paradigm in place at the time of enactment.

However, after the passage of thirteen years, the Oddzon court held that prior art under sections 102(f) or (g) could be used to determine the obviousness of an invention in situations where (a) there was no common ownership or assignment of the invention and information being shared among the collaborators, and (b) the information exchanged was not publicly known. Effectively, the *Oddzon* decision creates a significant threat for the loss of intellectual property rights for inventors that engage in joint research projects with scientist from a different company or institution.

The solution is a legislative one. The Oddzon court itself invited Congress to re-

view its decision stating that "it is sometimes more important that a close question be settled one way or another than which way it is settled. We settle the issue here (subject of course to any late intervention by Congress . . .)." 122 F.3d at 1403.

 <sup>&</sup>lt;sup>3</sup> 122 F.3d 1396, 43 U.S. P.Q. 2d 1641 (Fed. Cir. 1997).
 <sup>4</sup> Section 103(c) was amended by the American Inventors Protection Act of 1999 to add Section (e) to the 103(c) exclusions.

<sup>5</sup> P.L. No. 98–622, 98th Cong., 2nd Sess. (1984), 98 Stat 3383

<sup>6</sup> See In re Bass, 474 F.2d 1276 (CCPA 1973) and In re Clemens, 622 F.2d 1029 (CCPA 1980).

Government-led initiatives to encourage the unhindered flow of information among scientists in the interest of meeting the technological needs of the country and maintain its technological leadership in the world are key elements in the consideration of the present initiative to recognize the adverse impact that the Oddzon decision is having on those broad goals. More immediate to the university sector is the potential loss of invaluable intellectual property rights and the delays or failure to achieve research goals where a collaborative effort would offer an opportunity to

efficaciously move ahead.

Chapter 18 of the Patent Act is of great value for universities as it provides retention of title of their intellectual property. Universities are also keenly aware of its objective, which is to utilize the patent system to transfer technology to the private sector for development of the technology in the marketplace. The private sector is fully aware of the Chapter 18 having interfaced with it for over 20 years, and appreciates that it affords a basis for protecting marketplace development and investment efforts. A significant factor in that university-private sector relationship is the willingness and opportunity to define ownership of an invention made jointly by those entities and the disposition of such jointly-owned inventions should the need arise. That opportunity under the proposed legislation should lay to rest voiced concerns about two patents directed to the same subject matter issuing to different parties in the event a collaborative arrangement is dissolved and afford a further spur to greater collaboration between the university and private sectors. This could readily result in more efficient development of products utilizing tax supported research results, and an increase in the transfer of technology for the public good.

Towards this end, we would propose a clarifying amendment to section 103 (c)

that would result in:

- increasing the flow of information among scientists at different institutions;
- · increasing the collaboration of scientists both within and without a given institution;
- promoting collaborations between the university and the private sector;
- promoting collaborations between government laboratories and the private sector as well as with the university sector; and
- enhancing the national pool of knowledge because of the greater unhindered flow of information among scientists.

The proposed amendment should be prospective only. Further, the amendment should not affect any final decision of a court or the Patent & Trademark Office that is rendered prior to the date of enactment and, should not affect the right of any party in any case pending before the PTO or a court on the date of enactment to have rights determined on the basis of the substantive law prior to the date of enactment.

#### IV. RELATED ISSUES

There is widespread recognition that the Bayh-Dole Act has been and continues to be successful beyond all expectations. It is unique in the world and is an essential component in the United States' global leadership in technology. At WARF, we receive numerous visitors each year from around the world. Invariably, our foreign visitors ask about statutory provisions in the patent law relating to patent rights in inventions made with federal assistance and express the wish that their own countries would adopt such forward-thinking legislation. This committee can be justifiably proud of the role it played in passing such a successful, landmark piece of legislation.

Yet, in spite of its undisputed success, there are continued attempts to alter the statutory framework so as to favor certain industries or groups. I trust that this Committee in its wisdom will safeguard such an important legacy of this committee

and oppose any legislation that compromises its demonstrated success.

#### V. CONCLUSION

Mr. Chairman, thank you again for your time and attention. In conclusion, I leave vou with three recommendations:

- an amendment to the Patent Act is necessary to promote collaborative research amongst the university and non-profit sector, the private sector and the government to achieve the promise of the 1984 amendments of this Subcommittee:
- an amendment which will, prospectively, reverse the holding in the Oddzon decision: and

protection of Chapter 18 of the Patent Act from amendments that compromise its demonstrated success.

If there are any questions, I will be pleased to answer them.

Mr. Coble. Thank you, Doctor.

Mr. Van Horn?

#### STATEMENT OF CHARLIE VAN HORN, ESQ., ON BEHALF OF THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

Mr. Van Horn. Thank you, Mr. Chairman. I am pleased to have the opportunity today to present the views-

Mr. Coble. Can you pull the mike a little closer to you, so that the back of the room can hear you? Thank you.

Mr. VAN HORN. Thank you.

I am pleased to have the opportunity today to present the views of the American Intellectual Property Law Association on the issues involved in promotion of collaborative research among nonprofit organizations.

As you know, section 103 of Title 35, one of the cornerstones of patentability in the United States setting forth the nonobviousness standard, has been amended twice in recent years to create exemp-

tions for certain types of prior art.

The legislative history for these amendments suggests that they were made to encourage communications among members of research teams and the patenting, where appropriate, of resulting team research to promote the public dissemination of the results of such collaborative activity.

These amendments, now embodied in section 103(c), limit the operation of these exemptions to employees of a single legal entity. In enacting these exemptions, legislative history makes clear that the principles of obviousness-type double patenting would apply where two patents would not have issued but for the section 103 statutory exemption.

AIPLA supports the Subcommittee's interest in seeking ways to promote collaborative research involving nonprofit organizations. However, AIPLA believes that special care needs to be taken with respect to any efforts to amend section 103(c), to ensure that it would not complicate the implementation of the section, create

traps for unwary collaborators, or lead to other undesirable results.

Our association is aware of one approach that has been suggested to address the perceived problem that would require that a prior established collaboration be present as a precondition to yet another section 103 exemption. As we understand this prior established collaboration exemption, it has at lest two fundamental flaws.

First, it creates some uncertainty because the courts would need to establish a judicial standard for whether the requisite collaboration had been established, and then determine whether the collaboration had been completed before or after the date of invention of the claimed subject matter. This additional uncertainty is likely to add to the workload of the Patent and Trademark Office, and we believe that placing additional burdens on the office, particularly at this time, and without additional resources, would not improve the patent system.

Secondly, a prior established collaboration exemption would seriously harm—or could seriously harm inventors and nonprofit organizations who disclose a basic idea of discovery to a collaborator. Consider, for example, a university professor who discloses a basic invention to an employee of a collaborating corporation. Because the basic invention would be disqualified as prior art under section 103(c), the corporation could obtain an array of patents on trivial, obvious modification, often before the university could successfully obtain a patent for the seminal idea.

Any patent application subsequently filed by the university would be blocked by obviousness-type double patenting on the basis of the patents previously issued to the corporation. The university would be faced with unattractive options that any patent it might obtain would be unenforceable unless it either acquired the cor-

porate patents or it assigned its patent to the corporation.

If this Subcommittee determines that a problem exists that can be most appropriately addressed through amendment of section 103(c), we believe that at least one approach that should be considered in fashioning an appropriate legislative remedy would be to focus on common ownership, not a prior established collaboration. Common ownership is an essential component of existing exemptions under section 103(c) and ensures that unjustified extensions of patent term of multiple patents for the same patentable invention are avoided, along with the possibility of harassment of members of the public faced with separately owned patents for the same patentable invention.

We thank and commend you, Mr. Chairman, for you continuing leadership in striving to improve our intellectual property system. The AIPLA looks forward to working with you and other Members of the Subcommittee in promoting collaborative research involving nonprofit organizations in ways that protect both the interests of nonprofit organizations and the public, and promote simple, predictable, and justifiable outcomes. Thank you.

[The prepared statement of Mr. Van Horn follows:]

#### PREPARED STATEMENT OF CHARLES E. VAN HORN

Mr. Chairman:

I am pleased to have the opportunity to present the views of the American Intellectual Property Law Association (AIPLA) on the question of amending 135 U.S.C. \$103 to promote collaborative research involving non-profit organizations including research institutes and universities. AIPLA recognizes the very important issues concerning inventions resulting from a joint collaboration involving employees from a non-profit organization, but is not convinced there is an urgent and compelling need to amend \$103(c) at this time. We believe that additional steps to encourage the patenting of inventions that cannot meet all the statutory requirements for patentability should be taken only after very careful deliberation. In the event that the Subcommittee determines that legislation is necessary, AIPLA believes that special care should be given to ensuring that it protects both the interests of universities and the public for the reasons explained below.

The AIPLA is a national bar association of more than 13,000 members engaged in private and corporate practice, in government service, and in the academic community. The AIPLA represents a wide and diverse spectrum of individuals, companies and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting

intellectual property.

#### BACKGROUND

An amendment to 35 U.S.C. § 103, enacted as part of the Patent Law Amendments Act of 1984, allows certain types of research teams to work together, but exempts prior art under 35 U.S.C. § 102(f) or (g) from being considered when determining whether an invention that is the product of that research team meets the statutory requirement for nonobviousness for a patentable invention. The legislative history states the rationale behind this amendment was to encourage communication. history states the rationale behind this amendment was to encourage communication among members of research teams and the patenting, where appropriate, of any resulting "team research," thereby promoting the public dissemination of the results of such collaborative activity. The American Inventors Protection Act of 1999 expanded this exemption to include prior art under 35 U.S.C. § 102(e). These amendments now appear in 35 U.S.C. § 103(c). The legislative history ("Section-By-Section Analysis of H.R. 6286, Patent Law Amendments Act of 1984," Congressional Record of October 1, 1984 at H10525 to H10529) of 35 U.S.C. § 103(c) makes clear that "obviousness-type double patenting" principles apply where two patents would not have issued, but for the § 103(c) statutory exemption.¹

The current § 103(c) exemption operates where only a "prior established assignment obligation" is in place among members of the processed to the p

ment obligation" is in place among members of the research team:

"Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.'

The current statute normally limits the operation of the exemption to employees of a single legal entity, i.e., within a university or corporation. AIPLA has undertaken to address the issue of whether this limitation should be expanded so that other inventors—inventors participating in other types of collaborations or otherwise—should have access to such an exemption from section 103 "prior art." <sup>2</sup>

#### AMENDING SECTION 103(C)

AIPLA supports the Subcommittee's interest in seeking ways to promote collaborative research involving non-profit organizations. If additional steps are considered necessary to promote collaborative research, it may be desirable to determine whether it is advisable to extend that promotion to other entities, in addition to non-profit organizations, that could establish small entity status including independent inventors and small business organizations, or even all inventive entities, both domestic and foreign. AIPLA believes that special care needs to be taken with respect to any efforts to amend 35 U.S.C. § 103(c) to ensure that it would not complicate the operation or implementation of this section and/or create traps for unwary collaborators.

In this regard, the Association is aware of at least one approach that would require a "prior established collaboration" as a precondition to the application of the § 103(c) exemption. This so-called "prior established collaboration" exemption has at least two fundamental flaws. First, the courts would need to establish a judicial standard for whether the requisite collaboration had been established, and then determine whether the establishment had been completed before or after the invention date for the claimed subject matter. Given the myriad of ways in which inventors interact with one another, the standard is likely to take the form of a complex, fact-dependent determination. Moreover, under the "duty of candor and good faith," anyone attempting to benefit from this provision would have an uncompromising duty of candor before the patent examiner to completely explain the nature and creation of the collaboration, as well as its existence relative to the invention date, that it

<sup>1 &</sup>quot;The Committee expects that the Patent and Trademark Office will reinstitute in appropriate circumstances the practice of rejecting claims in commonly owned applications of different inventive entities on the ground of double patenting. This will be necessary in order to prevent

inventive entities on the ground of double patenting. This will be necessary in order to prevent an organization from obtaining two or more patents with different expiration dates covering nearly identical subject matter. In accordance with established patent law doctrines, double patenting rejections can be overcome in certain circumstances by disclaiming the terminal portion of the term of the later patent, thereby eliminating the problem of extending patent life."

<sup>2</sup> AIPLA has assumed that any expansion of the effect of 35 U.S.C. § 103(c) in exempting subject matter from prior art would not change the application of "obviousness-type double patenting" to two resulting patents that, but for the section 103(c) exemption from prior art, could not have both validly issued. Such an exemption from double patenting for patents to the same patentable invention would contravene more than 100 years of judge-made law designed to protect the public from adversely held patents on mere obvious variations of the same invention. tect the public from adversely held patents on mere obvious variations of the same invention. See Miller v. Eagle Manufacturing Co., 151 U.S. 186 (1894).

is likely to needlessly generate issues of patent unenforceability. In addition, application of the standard would add to the workload of the patent examiner, who would be obliged to review these submissions and determine in the first instance if the requisite collaboration existed or, if it did not, what would represent prior art to be applied. We believe that placing additional burdens on the Patent and Trademark Office, particularly at this time and without additional resources, would not improve the patent system.

Second, the "prior established collaboration" exemption could seriously harm inventors, e.g., university inventors who disclose a basic idea or discovery under collaboration. One illustrative example of our concerns should suffice to demonstrate the gravity of the unfairness—and unworkability—for the "prior established collabo-

ration" test.

If a basic invention is disclosed by a university professor to an employee of a collaborating corporation, a § 103(c) amended to include a "prior established collaboration" option, would permit the corporate employee to quickly file an entire series of patent applications taking the original idea and making trivial modifications or other types of obvious selections or adaptations. Because the basic idea or discovery would be disqualified as prior art, the corporation could obtain an array of patents on trivial selections and adaptations, often before the university could successfully

obtain a patent for the seminal idea.

Any patent application subsequently filed by the university would be blocked by an "obviousness-type double patenting" rejection on the basis of the patents previously issued to the corporation. The university would be faced with the unattraction.

viously issued to the corporation. The university would be faced with the unattractive options that any patent it might obtain would be unenforceable unless it either acquired the corporate patents or it assigned its patent to the corporation.

Under the Patent Law Amendments Act of 1984, Congress directed that inventions patented as a result of §103(c) would be subject to "obviousness-type double patenting" and indicated that the United States Patent and Trademark Office should amend the double patenting practices before the Office to assure that appropriate double patenting rejections were made. By requiring the filing of terminal disclaimers, Congress ensured that unjustified extension of patent term of multiple patents for the same invention would be avoided, along with the possibility of harassment of members of the public faced with separately owned patents for the same assment of members of the public faced with separately owned patents for the same patentable invention. This is sound policy and the same direction to the United States Patent and Trademark Office should apply should any amendments be made

of \$103(c). If the Subcommittee determines that a problem exists that is most appropriately addressed through amendment of \$103(c), we believe that at least one approach that should be considered in fashioning an appropriate legislative remedy is to focus on "common ownership," not "established collaboration," since common ownership is essential in any event to enforceability under the well-recognized, necessarily applicable concepts of "obviousness-type double patenting." In addition, if amendments to \$103(c) are to be considered, consideration should also be given to the point in time at which this common ownership should be required. The current language in § 103(c) requires common ownership to exist "at the time the invention is made." A determination of when an invention is made can be a very complex undertaking and will often lead to the assignment of different dates for the inventions defined in different claims in a patent application or patent. Perhaps this determination is unnecessarily complex to achieve the goals of § 103(c) and a deadline such as the date a patent application is filed or a patent is issued would be a better and simpler approach. Finally, for the same reasons that motivated Congress in enacting the Patent Law Amendments Act of 1984, AIPLA believes that where two patents may issue, the principles of obviousness-type double patenting must continue to apply to avoid an unjustified extension of patent term on the same patentable invention, as well as to avoid the possibility of harassment of members of the public faced with separately owned patents for the same patentable invention.

#### CONCLUSION

AIPLA is eager to work towards simplification and strengthening of the patent laws and their application. We believe that any amendment to § 103(c) must be understandable, easy to determine and apply, and work to promote simple, predictable, and justifiable outcomes.

We, again, commend you, Mr. Chairman, for your continuing leadership in striving to improve our intellectual property system. The AIPLA looks forward to working with you, the other Members of the Subcommittee, and your able staff to support you in any way we can.

Mr. Coble. Thank you, Mr. Van Horn.

# STATEMENT OF JON GROSSMAN, ESQ., DICKSTEIN, SHAPIRO, MORIN & OSHINSKY LLP

Mr. GROSSMAN. Thank you, Mr. Chairman, Members of the Com-

mittee. I appreciate being invited to speak this morning.

When the resumes were read off a little bit earlier, a number of my clients were mentioned. These are university clients. I am here to represent myself and my views as a private practitioner, and I hope no one called my clients to let them know what I'm up to this morning.

I would like to talk a little bit about my experiences and—

Mr. COBLE. Mr. Grossman, I cannot guarantee—we cannot insulate you with certainty on that. [Laughter.]

You are assuming the risks from hereon in.

Mr. GROSSMAN. Thank you very much, Mr. Chairman. I'll take that risk.

I would like to, however, talk a little bit about my experiences and what I think the impact is going to be on these proposed ideas and changes to 103(c).

As my understanding goes, and my practice has encountered 103(c) on a few occasions, it has been my understanding that its purpose is to allow free communications among researchers.

In the 1997 *OddzOn* decision, the court restricted the scope of 103(c) to communications between researchers working within an inventive entity. I think the court correctly concluded that that was a restricted case, and I think that there was some concern that *OddzOn* would create a chilling effect on research collaborations, because collaboratively developed inventions were not entitled to the same benefits that 103(c) states.

I do not believe, however, that OddzOn severely threatens collaborative research. In my 16 years in private practice, and in my 3 or 4 years as a patent examiner, I have not encountered 103(c) once. When I conducted a very unscientific poll of my colleagues in our 55-person patent practice, I only found two occasions that people had come across where 103(c) had an impact.

So from my standpoint, if there is a 103(c) issue, and certainly there is a lot of collaboration going on, why is there not a problem? Well, I think I have a couple of explanations, from my standpoint.

First, by and large, most universities that I've encountered that engage in collaborative research are able to easily ferret out inventions quickly and protect them.

Each researcher has a good idea of what he or she contributes to the effort, as well as those contributions of their respective colleagues. After all, academia is incredibly competitive, and achieving credit from one's work is a researcher's raison d'etre.

Second, if a researcher can foresee a potential prior art problem, he or she often takes steps to anticipate or avoid it. They can file a patent application on a subsequent invention as a continuation

or a continuation in part.

Third, prior art problems can be avoided by the inventor by disclosing an invention as soon as they can. This Congress created the provisional patent filing system. This makes it nice and easy.

Provisional patent applications are informal filings that are assembled quickly. Sometimes a provisional patent filing is little more than a draft paper, a long-winded e-mail, or informal notes. These easy and inexpensive filings dramatically improve the ability of researchers to freely disclose their inventions almost imme-

diately after conception.

Fourth, and I think most importantly, in terms of what I've come across, it is rare that any institution desires joint ownership of IP. Patent rights that are jointly owned are somewhat like a bad marriage, from my experience. There are no rules of the road. Each entity owns one-half of an undivided whole. There is no duty of accounting. To the extent that there is a collaborative effort, my dealings with universities have tended to move more greatly toward how to break apart rights and how to individually own those rights. For those situations, Members of this Committee, I urge you that 103(c) works quite well.

Moreover, I think broadening the impact and the meaning of 103(c) may lead to worse problems than OddzOn. My first concern is that it may create what I would call an anti-competitive effect.

Universities are not the only entities that do collaborative research. Companies of course do it all the time. If would be competitors are able to carve out prior art under 103(c), this would allow them to receive substantially broader patent rights.

Moreover, if their smaller competitors can't take part in this collaborative effort, they receive a double whammy. They would not receive the full benefits of 103(c) as amended, and they would be subject to increased enforcement activity or higher license fees.

Finally, with the few seconds that I have left, I would just like to mention that the present proposal could be an administrative burden on the Patent and Trademark Office. Under some suggestions, the proposed amendment would require that patent examiners make legal judgments under the rules of evidence, determining whether or not a party seeking to prove the existence of a research collaboration has met his or her burden in establishing the collaboration.

Many patent examiners are not lawyers and do not understand the rules of evidence. To the extent patent examiners make legal judgments, those are constrained to questions of patent law.

In my experience, this would become a burden to the Patent Office if the proposal does not make this an easy and quick way to

make determinations.

Finally, this proposal, at least the one that I have seen regarding 103(c) in broadening it, may have an impact on other forms of patent practice. I don't want to put this Committee to sleep, but there's a patent practice knows as double patenting, which is solved by something called "the terminal disclaimer."

Those practices right now, as they work, only work for a commonly owner entity and they would have to be changed in order to make practitioners work under a dual-owned scenario, as proposed

by amending section 103(c), if it were expanded.

In summary, I think it is a worthwhile endeavor for the Subcommittee to consider measures to improve America's competitive edge. Clearly, collaborative research should be encouraged in a manner that has an overall positive effect. The present proposal to amend 103(c), however, has the potential to complicate patent practice, create additional burdens on the Patent Office, and harm competition.

I, therefore, respectfully urge that this Subcommittee not amend 103(c) as presently proposed. Thank you.

[The prepared statement of Mr. Grossman follows:]

#### PREPARED STATEMENT OF JON D. GROSSMAN

Mr. Chairman: I appreciate the opportunity to appear before this Subcommittee. I am a patent practitioner in private practice with over 20 years of patent experience and I represent a number of different clients, including several major research universities. My testimony today does not necessarily reflect the views of my clients.

#### I. BACKGROUND

My comments today pertain to oversight by this Subcommittee regarding proposed legislation amending or reinterpreting Section 103(c) of Title 35 of the United States

The primary purpose of Section 103(c) is to allow free communication among re-The primary purpose of Section 103(c) is to allow free communication among researchers within an organization concerning invention developments. In 1997, a decision by the U.S. Court of Appeals for the Federal Circuit, OddzON Products, Inc. v. Just Toys, Inc. 122 F.3d 1396, 43 U.S.P.Q. 2d 1641 (Fed. Cir. 1997) restricted the scope of Section 103(c) to communications between researchers working within an organization. The OddzON Court concluded that Section 103(c) did not apply to communications outside an organization or between organizations. Accordingly, some have concluded that the impact of OddzON was to create a "chilling effect" on research collaborations because collaboratively developed inventions were not entitled to the same benefits under 103(c) as researchers working for a single entity. To avoid the problems that arise from OddzON, it is my understanding that this Subcommittee is reviewing the possibility of amending or clarifying the interpreta-

Subcommittee is reviewing the possibility of amending or clarifying the interpretation of Section 103(c) to extend the protection afforded by this Section to include collaborative research arrangements. The intent of the amendment or reinterpretation is to preclude obviousness rejections of an invention, as claimed in a patent application, or invalidation of a patent on obviousness grounds based on subject matter developed by any members of the collaborative effort and which qualifies as prior art only under Sections 102(e), (f) or (g) of Title 35.

It is my conclusion that, to the extent Section 103(c) contains weaknesses as revealed by the OddzON decision, those weakness may be tempered by a limited amendment restricting the expanded scope to federally funded research agreements with universities, small businesses, and non-profit organizations in line with The Bayh-Dole Act of 1980<sup>2</sup>, The Stevenson-Wydler Technology Innovation Act of 1980<sup>3</sup>, and The Small Business Technology Transfer Act of 1992<sup>4</sup>. In particular, I am concerned that broadening the scope or meaning of Section 103(c) may cause unintended problems that negatively impact the U.S. Patent & Trademark Office ("PTO"), complicate patent practice, and harm competition.

#### II. COLLABORATIVE RESEARCH IS NOT SEVERELY THREATENED BY OddzON

There is no doubt that collaborative research is an important part of the engine that drives our economy. Researchers from different institutions need to freely communicate ideas and pool resources to create new inventions. It is not uncommon for prior developments to be used against a researcher's subsequent inventions. But this does not always result in a bar against patentability. In my 16 years in private practice, and in my several years as a patent examiner, I have rarely encountered obviousness rejections based on Section 102(e), (f) or (g) prior art that needed a Section 103(c) fix. Why is this?

By and large most universities that engage in collaborative research are able to easily ferret out inventions and quickly protect them. When there are joint institutional collaborations, each researcher usually knows what he or she contributes to the effort as well as those contributions of their respective colleagues. After all, academia is incredibly competitive and achieving credit for one's work is a researcher's

<sup>&</sup>lt;sup>1</sup>See Statement of Mike Remington submitted in support of amendment to 103(c), pg. 1.

<sup>&</sup>lt;sup>2</sup> 35 U.S.C. §§ 200 et seq. <sup>3</sup> 15 U.S.C. §§ 3701 et seq. <sup>4</sup> 15 U.S.C. §§ 638 et seq.

raison d'etre. Further, to the extent there are prior art collections that are relevant to on-going research, most researchers are sufficiently sophisticated to avoid the 102(e), (f) or (g) pitfalls. They know what was previously created, and they under-

stand the benefit of filing for patent protection.

If a researcher can foresee a potential prior art problem, he or she often takes steps to anticipate and avoid the problem. For example, if a potential patent applicant knows of another pending application which may potentially be considered prior art under Section 102(e), he or she can file a patent application for the subsequent invention as a continuation or continuation-in-part application (claiming priority to the prior application). The benefit of this practice is that the new patent application is afforded the same priority date as the prior application. Hence, the subject matter of the earlier application is eliminated as prior art, and any potential 102(e)-based rejection can be avoided.

Another way potential prior art problems can be avoided is by disclosing an invention as soon as possible after conception. This can be accomplished quickly by means of a provisional patent application. Provisional patent applications are informal filings that are assembled quickly. Sometimes the provisional patent filing is little more than a draft paper, a long-winded e-mail, or informal notes. These easy and inexpensive filings dramatically improve the ability of researchers to freely disclose their inventions almost immediately after conception. Thus, even universities with tiny budgets and without the availability of patent lawyers routinely protect their ideas well before they are communicated to outside collaborators. The filing of a provisional application allows the researcher up to a year to prepare and file a formal patent application, which will carry the filing date of the provisional application, as its effective date. Such early disclosure enables joint researchers to claim priority

tiny budgets and without the availability of patent lawyers routinely protect their ideas well before they are communicated to outside collaborators. The filing of a provisional application allows the researcher up to a year to prepare and file a formal patent application, which will carry the filing date of the provisional application, as its effective date. Such early disclosure enables joint researchers to claim priority dates behind many potential 102(e) references.

Moreover, it is rare that any institution desires joint ownership of intellectual property rights. For most institutions, the notion of joint ownership of intellectual property has all the qualities of a bad marriage. The patent rights owned by each co-owner involve inseparable rights with no "rules of the road" (each entity owns one half of an undivided whole interest) and no duty of accounting. Accordingly, to the extent that there is a collaborative effort, a great deal of attention is typically paid to how to break apart the rights, so that they are owned separately by each research partner. For these scenarios, Section 103(c) in its present form works well.

As a final matter of interest, most universities that I have represented simply do

As a final matter of interest, most universities that I have represented simply do not have massive patent prior art collections or disclosures. If there is a 102(e), (f) or (g) reference or disclosure to grapple with, then it can usually be solved by one of the previously elaborated approaches.

# III. BROADENING THE MEANING OF 103(C) MAY LEAD TO WORSE PROBLEMS THAN OddzON

It is critical that federal law aggressively promote collaborative research. From my standpoint, the best way for Congress to accomplish this important objective is to increase public funding, provide tax incentives, and institute programs such as those provided for in the Bayh-Dole Act of 1980 and the Stevenson-Wydler Technology Innovation Act of 1980. Promoting collaborative research through the patent laws, however, requires great care in order to avoid creating worse problems elsewhere.

#### A. Amending 103(c) May Have An Anti-Competitive Effect

The biggest concern that I have with the proposed amendment to  $\S 103(c)$  is the potential loophole it creates. Universities are not the only entities that do collaborative research. Companies do it all the time. And with companies, it is not inconceivable that a change to 103(c), such as the one proposed to extend the protection to all joint research and development arrangements, could create an anti-competitive effect.

Many areas of technology have one or two dominant companies and a number of small competitors. Not surprisingly, the big competitors file lots of patent applications and therefore own lots of patents. In fact, it is common for large corporations to have a steady stream of new patents issue in their respective patent portfolios. They have sophisticated patent programs in place, and receive lots of attention and advice from in-house and outside counsels. If two big competitors were to set up a "joint research agreement," companies such as these would be the primary beneficiaries of the amended or re-interpreted 103(c), which would allow them to receive substantially broader patents and also more patents than under the present statutory boundaries.

Moreover, if smaller competitors were not invited to join in the collaborative efforts they would get a "double-whammy:" They would not receive the full benefits

of 103(c) and/or they would be subject to increased enforcement activity and/or high-

Even if the amendments to 103(c) were restricted to non-profit and university collaborators, there would still be problems. For example, a number of my university clients conduct research funded by commercial interests. Indeed, this is a soughtafter arrangement. Typically, a for-profit company funds the university's basic research. The company funding has strings attached in the form of an obligation by the university to assign to the company any patents that emanate from the funded research. If Section 103(c) were just restricted to non-profit institutional collaborations, smaller businesses would again be hurt by large corporations squeezing them out of favorable collaborative arrangements with the non-profits, especially if the patent rights were subsequently assigned to the large companies. Any amendment to 103(c) thus should be limited to federally funded collaboration projects which already carry protective restrictions in favor of non-profit organizations, universities, and small business entities.

#### B. Amending 103(c) Will Create An Administrative Burden On The PTO

A further problem with the proposed legislation is that it would have problematic impacts on other aspects of patent practice. The proposed amendment would require that patent examiners make legal judgments under the rules of evidence to determine whether a party seeking to prove the existence of a research collaboration has met his or her burden in establishing the collaboration's existence. Many patent examiners are not lawyers, and do not understand the rules of evidence. To the extent patent examiners make legal judgments, those judgments are constrained to questions of obviousness, novelty and other aspects of patentability based on the requirements of Title 35 and its related rules under the Code of Federal Regulations and the Manual of Patent Examining Procedures. It would be a burden on the PTO to train examiners to understand substantive contract law and the Federal Rules of Evidence. It would also be a burden on examiners to review, understand and judge the merits of the documents submitted in support of the existence of a joint research collaboration

A potential solution to this problem could be to promulgate additional rules which simply place the burden on the patent applicant to judge the sufficiency of evidence to support a joint research collaboration that qualifies under amended section 103(c). To claim this benefit, all that would be needed would be a clear and conspicuous statement having prescribed language similar to that currently used by patent applicants to establish common ownership of an application and prior inven-

#### C. Amending 103(c) Will Create Double Patenting Problems

Another concern is the impact of the changes to 103(c) on double patenting issues. It is common when there is a 35 U.S.C. § 103 rejection based on 102(e) prior art

for the examiner to also frame a rejection based on double patenting.

Double patenting arises from the principle that one individual or entity cannot be granted more than one patent covering a single invention. The "one invention one patent "rule is not a prior art based rejection. Rather, it is based on the statutory language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process, machine, manufacture or composition of matter . . . may obtain a patent therefore." The prohibition against double patenting is also critical in preventing patent owners from impermissibly extending the effective term of a patent. Finally, it avoids the problem of subjecting third parties to having to pay royalties to multiple patent holders for the same or substantially the same inven-

Typically, a double patenting rejection is easily overcome by filing what is known as a terminal disclaimer. A terminal disclaimer causes the term of the second patent to expire at the same time as the first patent. A terminal disclaimer also declares that during the undisclaimed portion of the patent term, the disclaimed patent would only be enforceable for so long as both patents remained under common ownership. So, if you have one patent application with claims that overlap the claims of a second application (or patent), the effects of the terminal disclaimer will be to give the same term and common enforcement rights to both.

Presently, terminal disclaimers are only available to the common owner of both the pending application and the prior application or patent. If 103(c) were amended to allow 102(e) based prior art to be disqualified on the basis of an established joint research agreement, however, you could potentially have two (or more) patents issue with patentably indistinct or overlapping claims, owned by different entities. Filing

<sup>&</sup>lt;sup>5</sup> Manual of Patent Examining Procedure (MPEP) § 706.02(l)(2).

a terminal disclaimer would not be available as a remedy because of the different ownership between the application and the 102(e) reference. Thus, if Congress were to amend 103(c) as proposed, there would have to be similar changes implemented

in the rules for double patenting and terminal disclaimer practice.<sup>6</sup>

The current proposal to amend 103(c) provides the remedy of including a requirement that the information shared in the research collaboration not have been disclosed or claimed in an earlier filed patent application. More specifically, it is proposed that any amendment to 103(c) be expanded, with respect to joint research arrangements, to enable disqualification of 102(f) based prior art, but not 102(e) based prior art. Also, joint research applicants should only be able to disqualify section 102(g) based prior art if that art has not been publicly disclosed, such as in a prior patent, publication, or otherwise. This alternative requirement may also go a long way toward avoiding the terminal disclaimer conundrum.

#### IV. CONCLUSION

In summary, it is a worthwhile endeavor for the Subcommittee to consider measures to improve America's competitive edge. Clearly, collaborative research should be encouraged in a manner which has an overall positive impact. The present proposal to amend 103(c) however has the potential to complicate patent practice, create additional burdens to the PTO and harm competition. I therefore respectfully urge that this Subcommittee not amend Section 103(c) as presently proposed.

Mr. Coble. Thank you, Mr. Grossman.

We apply the 5-minute rule to us, as well, so the red light shines

in our eyes, so let me get moving here.

First, to Dr. Gulbrandsen and Mr. Rivette, in response to Mr. Grossman's testimony and his statement that "by and large, universities do not have a need for the protections offered under section 103(c)"-now, Mr. Grossman has suggested that the provisional application process, for example, is a good and viable substitute.

What do you all say? Dr. Gulbrandsen first, then Mr. Rivette.

Mr. Gulbrandsen. I would disagree with Mr. Grossman, that collaborative activity is not an increasingly important aspect of university research, both with the private sector and with other universities, and that this case does have a chilling effect.

The suggestions that he made with respect to what precautions researchers could take in order to avoid the problems of OddzOn really gives researchers much more credit for being astute patent practitioners than they really are. I work with researchers every day, and researchers really are not interested in what is and what

ties.

7 This is similar to the prior art set currently identified in 35 U.S.C. § 102(a), which states that an invention is unpatentable if "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent" (emphasis added). It is proposed here, however that the requirement in the 103(c) amendment disallow the invocation of 103(c) where the prior art was disclosed, i.e., know or used, in any foreign country, in addition to in the U.S.

<sup>&</sup>lt;sup>6</sup> Although this problem created by the proposed expansion of section 103(c) is serious one, <sup>6</sup>Although this problem created by the proposed expansion of section 103(c) is serious one, the double patenting concerns can be adequately addressed by also revisiting the rules for making double patenting rejections and for the requirements of a terminal disclaimer to overcome those rejections. Patent examiners must be allowed to make double patenting rejections (or provisional double patenting rejections where the prior art is an application) upon a showing of a joint venture relationship submitted to eliminate a qualifying piece of prior art cited in an obviousness rejections. The revised double patenting rules could be based on the identity of a common inventor or a common assignee among the inventive entities or the ownership entities of the subject application and the prior application or patent. The requirements for terminal disclaimers could be changed to require that, where the terminal disclaimer is submitted to overcome a double patenting rejection and a joint venture relationship has been established in the claimers could be changed to require that, where the terminal disclaimer is submitted to overcome a double patenting rejection and a joint venture relationship has been established in the record, any patent maturing from the subject application would remain enforceable for only so long as the owner of the prior patent (or application) is also a joint owner of the prospective patent. An additional requirement should be added for the other joint owner(s) of the subject application to agree not to seek enforcement of the prospective patent against third parties independently of the overlapping owner of the subject application and the prior patent or application. These provisions should also be made binding on any heirs and assigns of the current parties

isn't prior art. They're interested in free flow of information. So they are not going to take the kind of precautions that Mr. Grossman talked about. And if they did take the kind of precautions he talked about, the free flow of information would stop.

Mr. Coble. Mr. Rivette?

Mr. RIVETTE. Yes, I agree with Carl. I think there are two issues here.

Expounding on what Carl said, I do believe that he's correct in characterizing the research DNA, if you will, as different than the patent attorney DNA. The researchers do not look, most of the time, at what is patentable. They just want to get in the research.

The other issue is the collaboration itself is designed specifically to come up with new discoveries. This is the area where the provisional applications may or may not be appropriate, because you have more than one person working on it. The collaboration itself will result in the discoveries.

The second area that was discussed was the dual ownership. Yes, I agree Mr. Grossman that dual ownership is a problem and that people run to find some ways to resolve it. But that's what the licensing provisions are for. Those are things that private industry and nonprofits, or between private industry, have resolved many times in licensing arrangements. And I would suggest that, in that situation, you fall back on the licensing, the Licensing Executive Society, or whatever else, to look at those issues.

Mr. COBLE. Thank you, sir.

Messrs. Van Horn and Grossman, let me put this question jointly

to you all, two-part question.

It is argued that in the *OddzOn* case, the court narrowly construed the amendments to section 103(c) of the Patent Act. Do you agree with that analysis, A? B, in your view as someone who is responsible for giving legal advice to your clients, did the *OddzOn* case change anything in how you would recommend universities proceed with their collaborations?

Mr. Van Horn, do you want to go first? Mr. Van Horn. Thank you, Mr. Chairman.

I guess I would come at that question from a different perspec-

tive than Mr. Grossman.

In 1984, when the law was amended to basically enact section 103(c) as it pertained to sections 102(f) and (g), I was in the Patent and Trademark Office. And at that time, the Patent and Trademark Office issued guidance to the examiners on how this particular section should be implemented.

The *OddzOn* case simply confirmed the instructions and guidance that the Patent and Trademark Office had given examiners. So from my perspective, that didn't change anything. It simply confirmed the guidance that the Patent and Trademark Office had given to examiners was, in fact, correct.

So it's not something—I've only been advising clients for the last 7 years, but the *OddzOn* case certainly did not change anything I have done in those 7 years.

Mr. COBLE. Thank you, sir.

Mr. Grossman?

Mr. GROSSMAN. I guess my first response would be, since I never had to deal with 103(c), there was really not much of a change in

my practice prior or before it. It really wasn't an issue that was coming up with my university clients or my other clients, for that

matter, very frequently.

But my reading of the *OddzOn* case fit precisely with my understanding of the statute, that it was a fairly limited rule, carving out a very important aspect of the Patent Act, section 103, which every practitioner and examiner lives and breathes by. And that was a fairly narrow, constrained carve-out, only limited to common entities that owned these rights.

That was my understanding, and OddzOn has done nothing to

change that understanding, sir.

Mr. COBLE. I see my red light appears. I have other questions, but we're going to have a second round here.

I am pleased to welcome the gentlelady from Pennsylvania, Ms. Hart, and the gentleman from California, Mr. Issa.

I am now pleased to recognize Mr. Berman, the gentleman from California.

Mr. Berman. At a very simple level, which is the level I prefer in this area, there generally seems to be—there are two different trends going on right now.

The issue involved here is in the context of wanting to promote collaborative research to increase knowledge, develop new products, help the economy, and just sort of help the progress of the species. We ought to do something here to facilitate the ability to get a patent and thereby incentivize all of that.

Today, one of our colleagues is introducing a bill, in order to promote research and increase knowledge and improve the condition of the species, that would exempt research for noncommercial purposes from having to get the approval of the patent-holder.

Mr. Rivette, I'd start with you. Where do you think the exemption for noncommercial research would fit in, in terms of making

collaborative research easier or more difficult?

Mr. RIVETTE. Let me restate it so that I'm sure that I'm answering the right question.

Mr. Berman. I'm not even sure I'm asking the right question. [Laughter.]

Mr. RIVETTE. What I—my——

Mr. Berman. It's beyond the scope of the narrow question involving this—

Mr. RIVETTE. Right.

Mr. Berman.—103(c) or whatever.

Mr. RIVETTE. Yes, Representative Berman, I think the issue here is one of the exemption being for noncommercial use, if I'm correct. And that's the basis that you're looking at.

I think it's a slippery slope. I think it's a very difficult distinction to make many times, because what's noncommercial today can be

commercial nanoseconds later, we've found many times.

I think that—for a number of areas, I think that the National Institute of Health, I think the National Science Foundation, a number of others, have got some guidelines on some of this that I've seen. They specifically talk about the issues of research products being exempt so that the mechanisms for enhancing research are available. I would support that.

But I do think we should go through the process of patenting them. I think that not patenting those things is incorrect. I've always believed that if we're going to have the process, we should

patent it.

I think that those discoveries should be put in front of the Patent Office to have it examined. And then, at the end of the day, if it's determined that they are patentable subject matter and that they patentable inventions, that at that point we should look at an exemption. But I think it should be very narrowly defined.

I don't think it should be something that allows a lot of commercialization to go on under the guise that it's just a pure research

project. And that's where my concern comes out.

Mr. BERMAN. Do any of you have different views on this?

Mr. Gulbrandsen. I think that there is—certainly there is court-case-made law that defines very narrow research exemption from

infringement as long as it's for purely philosophic use.

WARF, in its part, certainly every time we enter into a license agreement with a company, we retain a license back, not only to our own technology for research at the University of Wisconsin-Madison, but in the improvement technology that is made by that company for research at the University of Wisconsin.

Mr. BERMAN. Say that again. For what?

Mr. GULBRANDSEN. In all of our license agreements, we provide a grant back to the University of Wisconsin-Madison that we use not only our own technology but improvements to that technology by the licensee for research at the University of Wisconsin-Madison. So we take care of that by license.

And I think that the organization BIO has gone on record as saying all its members would not enforce their patents against re-

searchers that are doing purely scientific research.

So I think the marketplace has, to a certain extent, taken care of that exemption.

Mr. BERMAN. My time is up. Thank you.

Mr. COBLE. Thank you.

The gentlelady from Pennsylvania?

Ms. HART. I have no questions.

Mr. Coble. Ms. Hart?

Ms. HART. I have no questions.

Mr. COBLE. Thank you.

The gentlelady from Wisconsin, Ms. Baldwin. Ms. BALDWIN. Thank you, Mr. Chairman.

What I heard in the testimony was two alternative legislative approaches and a recommendation that we not alter 103(c) through legislation. And I've heard some comment back and forth on taking action versus not. But I haven't heard any response to Mr. Van Horn's alternative legislative proposal, which is to use common ownership, as I recall your testimony, versus a prior established collaboration requirement. And I wonder if I might hear some com-

ment to that legislative approach.

Mr. Gulbrandsen?

Mr. GULBRANDSEN. Yes. My own opinion is that common ownership doesn't solve the problem. In Wisconsin's case and in the case of most universities that are operating, that are licensing federally funded inventions, there is a prohibition against assignment of ownership under the Bayh-Dole Act. We cannot assign ownership to another entity without permission of the funding agency.

And as a matter of policy at Wisconsin, we just do not do that. So joint ownership is a way of life for us, and we handle that

through licensing.

The problem with the *OddzOn* case is a problem of dealing with secret prior art in collaborations. And I can just give you one example at Wisconsin where the *OddzOn* case creates a real threat, and that is a major research collaboration that we have with industry

in the area of medical imaging.

There is a large manufacturer of imaging devices in the market-place that shares its source code with the University of Wisconsin-Madison. This is a long-standing agreement that was in place even before OddzOn. If OddzOn were to have happened before that agreement, I doubt that they would have entered into it, for fear the problems that would have caused with them sharing their source code with us.

And this is a very, very critical research program that is going to create great technology for everybody. And we wouldn't be able to do without that collaboration.

Ms. Baldwin. Mr. Rivette, did you have a comment on—

Mr. RIVETTE. I'll just second it. I think Carl is absolutely right. I think these are the sort of things that—OddzOn, in my reading of it, does put an impediment there. It may cause a chilling effect from the standpoint that you'll have attorneys walking into the process of discovery, saying, "I really don't think we should be disclosing this." If that occurs, I think we're going to slow this whole process down.

Ms. BALDWIN. Thank you.

Mr. Coble. Thank you, Ms. Baldwin.

Professor, Dr. Gulbrandsen, I want to put part B to the question I put to Mr. Van Horn and Mr. Grossman to you.

How, in any way, did the *OddzOn* decision change the manner in which you would recommend universities to proceed with their

collaborations, if any change at all?

Mr. GULBRANDSEN. It has certainly raised our awareness of the issues of secret prior art. It's made our agreements much more complicated. I was recently at the Association of University Technology Managers' meeting, and at that meeting, we talked about this case.

And, in fact, examples came out where collaborative ventures, in fact, were scrapped because of fear that this was putting the company at jeopardy or putting the university at jeopardy with respect to any jointly owned inventions.

So I think that, from our standpoint, it's just increased the cost of operation. It's increased the difficulty of doing the collaborations

that we should be doing.

Mr. COBLE. Mr. Rivette, everyone but you has placed an oar into these waters. Do you want to involve yourself with this question?

these waters. Do you want to involve yourself with this question? Mr. RIVETTE. Well, I'll involve myself more from the standpoint of the private industry looking at a joint venture or looking at doing collaborative work. And, again, I will probably go with what Carl said, and that is, I would, having run companies and having done collaborative work, I would have said no. I would have stood

back a little more. I would have asked questions. I would have slowed down the process, because if I could not find protection, if I could not put my resources, which are dollars, for my shareholders in a position that I could get protected technology coming out the other side, I'd probably make another decision.

So I guess here I don't see this as an issue—as a big problem. I see this as something that needs correction and that we could cor-

rect it fairly quickly.

Mr. Coble. Thank you, sir.

Mr. Berman?

Mr. BERMAN. Mr. Grossman, you're concerned about the potential for anti-competitive practices for private companies, if we were to amend 103(c), as I understand it.

Mr. Grossman. Yes, sir.

Mr. BERMAN. Why does a proposed change imply that it would waive—constitute a waiver of antitrust law? Can we make it clear that antitrust laws are still applicable, that if we were to add such a provision to any amendment that made it quite clear that nothing in this bill is deemed to in any way implicate the application of antitrust laws?

Mr. Grossman. Yes, I think that that could be one way to address the issue of anti-competitiveness with regard to making a

joint research.

The concern I have is that it doesn't really—it's not really tying. It's not really an attempt to monopolize under the antitrust laws. It's really that the effort of joining two large companies together to, if you will, hog the patent pool, could harm competition. I think that would be one way to address it.

Quite honestly, I think another way to address it would be to restrict subsequent uses of those patents only for nonprofit research, and any assignment or attempt to assign those patent rights by, let's say, a university to a private company would render that unenforceable in the context of subsequent litigation by a private entity.

Mr. BERMAN. That's something you're suggesting?

Mr. GROSSMAN. Yes, sir, it is something that I'm suggesting, Mr.

Mr. Berman. Well, given the Justice Department's seeming disinterest in the consolidation of big companies, I'm not quite sure to what extent the public should be more concerned about two big companies working out common agreements here.

But in any event, let me ask Dr. Gulbrandsen, if we did this amendment, what would the collaborators need to do in order to formally declare themselves as partners? How different would it be from the current standard practice? And what would be the impact

on how research is done and collaborations are developed?

Mr. GULBRANDSEN. Frankly, I don't think it would affect the present practice enormously. What I think it would do is make the present practice much safer than what we have right now. We do enter into inter-institutional research agreements with other non-profit organizations and with companies. These agreement would be evidence of that collaboration. And then jointly owned inventions that arise out of it would have the benefit of this amendment.

So I think, at a minimum, you would need an agreement in

place.

Mr. Berman. In other words, you're doing these things, having these agreements, and this case came down and now you're a little worried about the extent to which those agreements really protect you from all of these problems you've talked about?

Mr. GULBRANDSEN. Well, I would say we're more than a little

worried. [Laughter.]

We're very worried. And these agreements won't protect us right now.

Mr. Berman. So, basically, what—you want to change the law to make sure those agreements are——

Mr. Gulbrandsen. That's right.

Mr. Berman.—continue to be effective.

Mr. Gulbrandsen. That's right.

Mr. BERMAN. Thank you, Mr. Chairman. Mr. Coble. Thank you, Mr. Berman.

The gentleman from California, Mr. Issa, do you have questions? Mr. Issa. I'd like to waive questions. I'm just enjoying learning another new part of patent law.

Mr. COBLE. Good to have you with us, Mr. Issa. Ms. Hart, the gentlelady from Pennsylvania?

Ms. HART. I'm sorry. I'm sort of in the same boat as Mr. Issa. But I do have a general question, and it's for the panel, because I represent the Pittsburgh area, and we have a lot of, obviously, pretty cutting-edge research going on at Carnegie Mellon University, the University of the Pittsburgh, all pretty much in collaboration with some State efforts, some Federal efforts. And, obviously, we have an interest in making sure that that continues.

I guess—I mean, I read through some of the testimony. I guess as far as sort of a future vision, do you see—maybe that's the

wrong question.

Do each of the panelists believe that that is the best atmosphere for us to come up with better innovations? And if it isn't, could you tell me what a better mix might be? And this is very general, so if you have a thought on it, great. If you don't, tell me I'm crazy and that's fine, because I think a lot of people think, in some ways, that's a little disorganized as well, that we ought to have certain things in certain places. We certainly don't have it that way at this writing, and we don't in our area, for sure.

Mr. GULBRANDSEN. Can I ask you, are you asking, is the collaboration between the small startup companies and universities the

best way to do innovation in this country?

Ms. HART. That's basically what my question is, yes.

Mr. GULBRANDSEN. Okay, well, I'll take the lead on that question.

I think in areas of university technology, for example, the technology that we transfer out of the university is very early stage. Most large companies are not going to take a risk on trying to develop this early stage technology, where, in many cases, there's not even a market yet. And so what has evolved in this country is the phenomenon of startup companies that are willing to take the risk, and venture investors that are willing to put their money in those startup companies.

This model is really working in this country, and it is being copied by every major industrial country in the world. So it does work and it will—my hope is that it will continue to expand. And we do need this amendment to make sure that it does continue to expand.

Ms. Hart. At the risk of making my Chairman mad, okay, that having been said, that we're following the right model—however, I guess, we have the other piece, and I, unfortunately or fortunately, serve on the Science Committee. And we are, obviously, looking at another arm of research that's being done as well through Federal agencies. Do you see the basic research being done by the Government also as a necessity to that puzzle?

Mr. GULBRANDSEN. Absolutely. The strength of this country in high-technology really was—the foundation of that was laid for by the funding that started after World War II by the Federal Government at our universities and colleges, and that needs to continue. It's really a strength of economy, and we can't do without it.

Mr. RIVETTE. If I could? I truly believe that there are different forces at work here. You don't have a situation where the university research is distinct from other types of research or that the Federal Government or the State government research is distinct from the other types.

from the other types.

What you've got is a continuum, if you look at it, that many times the problems that are faced that the Federal Government may be perceived differently, will start different types of research. Those may then be followed up by the universities. And then I could almost look at it as startups being a mezzanine funding mechanism, and then you have a full productization mechanism with the larger organizations, which have full distribution and the ability to disseminate.

I think that is the right model, because it decentralizes a lot of the decision-making. So I would second that. I think that we actually have a good model. And it doesn't fit in a box, I guarantee.

Ms. HART. It just never will. Mr. RIVETTE. It never will.

Ms. HART. Thank you, Mr. Chairman.

Mr. Coble. Thank you. I thank the lady and the Subcommittee. Gentlemen, I appreciate your attendance today and your testimony.

This concludes the oversight hearing on patent law and nonprofit research collaboration. The record will remain open for 1 week.

Thank you again for your attendance today, and the Sub-committee stands adjourned.

[Whereupon, at 10:06 a.m., the Subcommittee was adjourned.]

# APPENDIX

#### MATERIAL SUBMITTED FOR THE HEARING RECORD

PREPARED STATEMENT OF THE HONORABLE DARRELL ISSA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. Chairman and Ranking Member Berman, I thank you for holding an Over-

sight Hearing on Patent Law and Non-Profit Research Collaboration.

I am very concerned that a possibility exists where public-private joint-ventures lead to patents being granted under Section 103 which might otherwise not previously have been granted. This is an issue of great concern to me and I look forward to exploring this issue in the coming months.

It has been my experience that the United States Patent and Trademark Office (USPTO) contributes to the number of lawsuits regarding patent infringements. Too often, the USPTO offers patents for improvements to original patents that should have been obvious to one of ordinary skill in the art at the time the improvement was made. I would argue that these situations should not warrant a patent, especially if the second patent application contributed nothing new and non-obvious to

Universities receive federal funding that go towards research, and with the research, they offer the information for public knowledge. On many occasions, the University parlays this research into patents and sells them to the private sector. I am concerned about these sales. Should universities continue to be allowed to do this or should something be done that brings the idea of secondary patents back into the proper prospective? I am also concerned about the USPTO issuing these patents under section 103 and the litigation that stems from them. This is an area of great interest to me and I will watch this very carefully as we discuss this issue in the future.

I thank the Chairman for scheduling this oversight hearing and look forward to hearing the testimony from this distinguished panel of witnesses.

# PREPARED STATEMENT OF JANET E. REED

## I. INTRODUCTION

My name is Janet E. Reed. I am a partner at the law firm of Woodcock Washburn LLP. I am a registered patent attorney, and also hold a Ph.D. in Biochemistry and an M.S. in Plant Pathology. I have been practicing intellectual property law for the past twelve years, during which time I have represented—and currently represent—numerous academic and commercial clients in all aspects of patent law. In particular, I have been involved on many occasions in structuring license and collaborative research arrangements between Government, academic and commercial partners. In addition to private law practice, I have also served as the director in charge of intellectual property of the University of Pennsylvania's Center for Technology Transfer. I have been a member of the Association of University Technology Managers since 1993, where I have performed a variety of committee functions, including service on the Government Relations Committee in 1998 and 1999.

I offer this testimony on behalf of the Association of University Technology Managers (AUTM). AUTM is an organization consisting of technology licensing profes-

agets (ACTM). ACTM is an organization consisting of technicogy incensing professionals in universities, non-profit organizations, government and the private sector. As technology licensing professionals, AUTM members routinely address situations involving collaborative research among different organizations and researchers, and work to ensure that patent rights arising out of such collaborations can be effectively.

tively licensed and commercialized.

#### II. THE IMPORTANCE OF COLLABORATIVE RESEARCH

Collaborative research among various private, public, and non-profit entities is extremely beneficial to the U.S. economy. A 1999 report of the National Research Council's Committee on Science, Engineering, and Public Policy found that partnerships among industry, academia and governments have greatly contributed to the recent technological successes in the United States, and the report recommended even stronger partnerships in the future. The report found that many large corporations reach out to universities, suppliers and subcontractors as sources of research. Similarly, technology-oriented start-up companies are highly reliant on university researchers to support basic research programs.2 The report also found that partnerships involving State and Federal Governments have played an increasingly important role in advancing the results of basic research into the commercial sector, to benefit the public at large.3

A 1998 report by the National Science Foundation (NSF) examined national trends in Research and Development (R&D) expenditures.<sup>4</sup> It found that there had been a major increase in the number of inter-sector collaborations since the early 1980s. More than 3,500 new cooperative research and development agreements (CRADAs) were created between 1992 and 1995 among Federal laboratories and other entities. These CRADAs allow private sector researchers to access and take advantage of the Government's R&D expertise and resources. Industry received an estimated \$20.8 billion in Federal R&D support in 1997. Nonprofit organizations and universities spent a record \$23.8 billion on research and development, the majority of which came from collaborations among institutions, commercial partners and government. Of the \$23.8 billion, \$14.2 billion was provided by the Federal Government through the National Institute of Health (NIH) and the NSF, \$1.8 billion by state and local governments, \$1.7 billion by industry, \$4.4 billion by the nonprofit organizations' or universities' own resources, with the remainder provided by miscellaneous sources. The income from these collaborations has also been substantial. Sales of products developed from inventions that were transferred from university or nonprofit research centers resulted in revenues of \$20.6 billion in 1996, and U.S. universities, hospitals and research institutes realized approximately \$500 million in gross license income in 1996.<sup>5</sup> The NSF report concluded that the increasing number of partnerships has efficiently shared resources and more effectively lever-

aged unique skills and research materials.

The U.S. Congress has promoted collaborative efforts to develop new inventions.

The Bayh-Dole Act of 1980<sup>6</sup> and the Stevenson-Wydler Technology Innovation Act of 1980 ("Stevenson-Wydler Act") were passed specifically to increase collaborations between the public, private, and nonprofit sectors. The Bayh-Dole Act states, in per-

tinent part, as follows:

It is the policy and objective of the Congress to . . . encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities . . . ?

Similarly, the Stevenson-Wydler Act provides:

The Congress finds and declares that . . . (3) Many new discoveries and advances in science occur in universities and Federal laboratories, while the application of this new knowledge to commercial and useful public purposes depends largely upon actions by business and labor. Cooperation among academia, Federal laboratories, labor, and industry, in such forms as technology transfer, personnel exchange, joint research projects, and others, should be renewed, expanded and strengthened.8

<sup>1 &</sup>quot;Capitalizing on Investments in Science and Technology," National Research Council, National Academy Press, 23–25; 49–51 (1999).

<sup>&</sup>lt;sup>3</sup>*Id*. at 24–25

 <sup>&</sup>lt;sup>3</sup> Id. at 24–25.
 <sup>4</sup> Science and Engineering Indicators 1998, Chapter 4: U.S. and International Research and Development: Funds and Alliances, report by the National Science Foundation. http://www.nsf.gov/sbe/srs/seind98/c4/c4h.htm. ["NSF Report"].
 <sup>5</sup> See Jane A. Biddle and Thomas D. Mays, Nonprofit-To-Industry Technology Transfers Grow, NAT'L L. J. C30 (October 19, 1998), citing AUTM Licensing Survey FY 1996, Association of University Technology Managers Inc., Norwalk, Conn. (1998).
 <sup>6</sup> Act of Dec. 12, 1980, Pub. L. No. 96–517, 94 Stat. 3015–28 (codified as amended at 35 U.S.C. 88 200 311 201 201 207.

<sup>\$\$200–211, 301–307).

735</sup> U.S.C. \$200.

815 U.S.C. \$3701.

It is the purpose of this chapter to improve the economic, environmental, and social well-being of the United States by—. . . (2) promoting technology development through establishment of cooperative research centers; (3) stimulating improved utilization of federally funded technology developments, including inventions, software, and training technologies, by State and local governments and the private sector; . . . 9

It is entirely clear from the Bayh-Dole and Stevenson-Wydler Acts that Congress recognizes the importance of collaborative inter-sector research, and the statistics demonstrate the success of these collaborations. Under the Stevenson-Wydler Act, the number of active cooperative research and development agreements between the Federal Government and other entities jumped from 98 in 1988 to about 1300 by the end of 1992. The number of licenses granted by Federal agencies rose from 128 in 1987 to 261 in 1991, and license income increased from about \$4.9 million in 1987 to over \$18 million in 1991.

State Governments have also recognized the importance of collaborative research. For example, the New York State legislature created the New York State Science and Technology Foundation, which is directed to "encourage and promote cooperative efforts among government, the private sector, and universities and colleges in the state for [the] purposes [of encouraging scientific and technological education, basic and applied research, and the development and fabrication of new commercial products]." <sup>11</sup> California created its Challenge Grant Program<sup>12</sup>, Maryland has established the Maryland Science, Engineering, and Technology Development Corporation <sup>13</sup>, and Illinois has enacted the Technology Advancement and Development Act 14, all for the same purpose of encouraging collaboration in research and devel-

Clearly, industry, universities, nonprofit organizations and governments all support collaborative research efforts. Nevertheless, as will be demonstrated below, the patent law, as interpreted by the Court of Appeals for the Federal Circuit (the Federal Circuit), may undermine these beneficial collaborations.

#### III. SECRET PRIOR ART UNDER 35 U.S.C. § 102 AND § 103

# A. Prior Art, Novelty and Non-Obviousness

Prior art—the body of information against which inventions are measured for patentability—consists generally of information found in patents, publication and in other publicly accessible forms, such as information disseminated through the Internet. Prior art is the primary "yardstick" against which inventions are measured for patentability. An invention whose elements are found entirely within the prior art, such as an earlier patent or technical publication, cannot be patented. Such an invention, under section 102 of title 35, United States Code, is not "novel." Similarly, an invention that varies from the prior art in a way that is "obvious" within the meaning of the patent statute cannot be patented pursuant to section 103 of title 35. United States Code. An invention must be both novel and nonobvious to be considered patentable over the prior art. The Patent and Trademark Office ("PTO") and courts rely on prior art when assessing the "novelty" and "nonobviousness" of an invention for which patent protection is sought.

In addition to several categories of publicly available information, section 102 also defines three categories of information that is not usually publicly available at the time a patent application is filed. The information defined in these categories, like information in an earlier patent or publication, can prevent a party from receiving a patent. These three categories of information are defined in subsections (e), (f) and (g) of section 102, and are particularly important in the context of collaborative research.

Section 102(e) concerns information contained in a patent that was filed prior to the date the application being examined was filed. Information in that patent will be "prior art" against a later filed application even if the patent had not been grant-

o 10 Sec Technology Transfer Under the Stevenson-Wydler Technology Innovation Act: The Second Biennial Report, Report of the Secretary of Commerce (January 1993), cited in Mark R. Wisond Bienman Report, Report of the Secretary of Commerce (January 1993), cited in Mark R. Wisner, Proposed Changes to the Laws Governing Ownership of Inventions Made with Federal Funding, 2 Tex. Intell. Prop. L.J. 193, 196 (1994).

11 N.Y. Pub. Auth. Law § 3101 (McKinney 1999).

12 CA Govt Code § 15379 (West 1990) ("The Legislature finds and declares all of the following:

<sup>. . . (</sup>e) The state should support collaborative research projects, involving the state, academia, and private industry, which have been carefully screened and offer a likely return on the state's

investment.")

<sup>13</sup> MD Code Ann. 1957, Art. 83A, § 5–2A–02 (1999).

<sup>14</sup> 20 IL Comp. Stat. Ann. § 700/1004 (West 1999).

ed at the time the later application was filed. Thus, information in the earlier-filed patent, even though it was not "publicly available" at the time an application was filed, can still prevent the issuance of a patent for the later-filed application.

The other two categories of information—namely, information falling into the definitions of paragraphs (f) and (g) of section 102—also can preclude the grant of a patent. Unlike sections (a), (b) and (e), however, the information defined in paragraphs (f) and (g) typically encompasses undocumented as well as undisclosed information, and information that may never be publicly disclosed.

- § 102(f) states that a person shall not be entitled to an invention if "he did not himself invent the subject matter sought to be patented." Section 102(f) ordinarily is implicated only where an applicant has "derived" the invention from another. 15 Derivation is demonstrated when (1) the party from whom the invention was derived possessed a complete conception of the invention and (2) there was a sufficient communication thereof to the party charged with derivation to enable one ordinarily skilled in the art to construct and successfully operate the invention. <sup>16</sup> When an applicant declares that he is the sole inventor, it takes strong evidence to reach a contrary conclusion.
- § 102(g) precludes an applicant from receiving a patent when the same invention had been made earlier by another person in the United States, if that invention had not been abandoned, suppressed, or concealed.<sup>17</sup> Section 102(g) does not require that the first invention be made public, only that it was reduced to practice and not abandoned, suppressed or concealed

The prohibition against the granting of a patent on the same invention that is disclosed in the prior art, or where the same invention was derived from or invented by another, under the circumstances defined in sections 102(e), (f) and (g), is appropriate and grounded upon solid public policy. However, where the new invention differs from the earlier invention, additional questions must be addressed.

If the invention is different from what is previously disclosed or communicated, the new invention must be compared to the old invention or information to assess whether or not a patent should be issued upon it. If the differences between the two are "obvious" within the meaning of the patent law, a second patent may not issue. If these differences are "nonobvious," both patents can be properly granted, each with a full 20-year from filing date term. And, as Congress has noted, if the information used to measure the obviousness of the invention is information defined in sections 102(f) and (g), additional questions must be addressed.

## B. The Special Status of Information in Sections 102(f) and (g)

Congress has recognized that information falling into the definition of sections 102(f) and (g) is distinct in character from information contained in documents that ultimately will be publicly disseminated (i.e., patents and printed publications), or which, at the time of the patent application, was publicly available (i.e., public prior use or sale of the invention). The fundamental distinction between section 102(f) and (g) information is reflected in section 103(c), which exempts such information from being considered relevant to measuring the patentability of the invention in certain circumstances, i.e., when the invention is owned or assigned to a common entity. In these circumstances, under section 103(c), information falling within sections 102(f) and (g) cannot be "combined" with other information to render an invention obvious." ¹

It also should be noted that an "inventor" in a 102(f) or (g) situation is ordinarily not a single individual but rather a group of individuals. This group of individuals is referred to as the "inventive entity." The information that is communicated among individual co-inventors within the "inventive entity" is not prior art within the group of \$102(f) and \$102(g) are as he expected the line between incoming of \$102(f) and \$102(g) are as he expected the line between incoming of \$102(f) and \$102(g) are as he expected the line between incoming of \$102(f) and \$102(g) are as he expected the line between incoming of \$102(g) and \$102(g) are as he expected the line between incoming of \$102(g) and \$102(g) are as he expected the line between incoming of \$102(g) are as he expected the line between the line between the line between the line between the line bexpected the line between the line between the line between the li the meaning of § 102(f) and § 102(g). As can be expected, the line between information that contributes to the invention versus information that existed prior to the invention is extremely difficult to draw in practice. Individual researchers in research team do not enter the "inventive" process with a blank slate and clear lines between knowledge and partial inventions. Moreover, they do not formulate all their ideas or concepts within an "inventive entity." Instead, many individuals bring to the research collaboration their knowledge, experience and even inventions that

<sup>15</sup> See Peter D. Rosenberg, Patent Law Fundamentals, at §7–97 (1999), citing Ex parte Billotet, 192 U.S.P.Q. 413 (P.O. Bd. App. 1976).

16 See Rosenberg. at 10–40, citing Davis v. Reddy, 620 F.2d 885, 889 (C.C.P.A. 1980); Mead v. McKirnan, 585 F.2d 504, 507 (C.C.P.A. 1978).

<sup>&</sup>lt;sup>17</sup>See Rosenberg at § 7–99. 18 Section 103(c) was amended by the American Inventor's Protection Act of 1999 to add section (e) to the 103(c) exclusions.

they developed outside the research project. This information, when shared by these individuals, however, falls within the scope of § 102(f) and § 102(g).

### C. Precedent Before 1984 Amendment to § 103

Before legislative intervention in 1984, federal courts had held that information falling into the definition of sections 102(f) and (g) may be combined with other "prior art" to render an invention "obvious" under section 103. In the precedential case of In Re Bass, the Court of Customs and Patent Appeals (CCPA)—the predecessor of the Court of Appeals for the Federal Circuit—held that prior inventions made by individual members of a research team constituted "prior art" under § 103.19 This decision was dramatic because it treated information shared among members of research team as "prior art" that could prevent an invention arising out of that research from being patented. It was the first time a court had combined § 102(g) and § 103 in a case not involving rival inventors in an interference procedure. 20 Instead, the court upheld an ex parte rejection of a patent application by the Patent and Trademark Office on statutory grounds. As the court held:

the use of a prior invention of another who had not abandoned, suppressed, or concealed it under the circumstances of this case which include the disclosure of such invention in an issued patent, is available as 'prior art' within the meaning of that term in § 103 by virtue of § 102(g).<sup>21</sup>

In reaching this conclusion, Judge Giles Rich, writing for the court, divided the provisions of section 102 into three categories, labeling subsections (c) and (d) as loss of right" provisions which had nothing to do with "prior art." Subsection (f) was considered irrelevant to "prior art," as it was more about the originality of the inventor than the novelty of the invention. He labeled the remaining four provisions the "prior art" provisions, stating:

Three of them, (a), (e), and (g), deal with events prior to the applicant's invention date and the other, (b), with events more than one year prior to the U.S. application date. These are the "prior art subsections.

Against this definition, the court's decisions in Bass and subsequent cases caused great concern to companies and other entities engaged in team research.

In 1980, the CCPA again addressed the relationship between §102(g) and §103 in *In Re Clemens*, and appeared to narrow the ruling from *Bass*.<sup>23</sup> The CCPA held that Bass should not be interpreted so that §102(g) applies to §103 when an inventor does not have personal knowledge about a prior invention:

W]here this other invention is unknown to both the applicant and the art at the time the applicant makes this invention, treating it as 35 USC s 103 prior art would establish a standard for patentability in which an applicant's contribution would be measured against secret prior art. Such a standard would be detrimental to the innovative spirit of the patent laws.

The Federal Circuit, in Kimberly-Clark Corporation v. Johnson & Johnson ("Kimberly-Clark"), rejected this construction and distinguished In Re Clemens as dictum.24 It stated that "§ 102(g) contains no personal knowledge requirement."25 This was confirmed by the Federal Circuit in E.I. Du Pont v. Phillips Petroleum Com-

D. Legislative History and Purpose of the 1984 Amendments to Overrule In re Bass In 1984, Congress enacted legislation to overrule In re Bass and its progeny.27 The amendment added the following language to § 103:

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

<sup>19 474</sup> F.2d 1276 (CCPA 1973).

<sup>&</sup>lt;sup>22</sup> 1d. at 1283. <sup>21</sup> 1d. at 1286–1287. <sup>22</sup> 474 F.2d at 1290. <sup>23</sup> 622 F.2d 1029 (CCPA 1980). <sup>24</sup> 745 F.2d 1437, 1445 (Fed. Cir. 1984).

<sup>&</sup>lt;sup>25</sup> *Id.* at 1445.

<sup>&</sup>lt;sup>26</sup> 849 F.2d 1430, 1437 (Fed. Cir. 1988).

<sup>&</sup>lt;sup>27</sup> Public Law 98–622.

A comparison of the first drafts of the legislation leading to these changes (H.R. 4525 and S. 1535) with the final legislation reveals important modifications. The final formulation tracks proposals made by the American Intellectual Property Law Association ("AIPLA"), and endorsed by, among others, Gerald J. Mossinghoff, who was Assistant Secretary and Commissioner of Patents and Trademarks at the time.28 The AIPLA drafted its language to deal with the specific problems created by In re Bass and In re Clemens related to research activities that occur entirely within organizations.<sup>29</sup> The AIPLA argued that the language in the earlier bills proposal was too broad, but did not explain why a broader, more proactive law was considered unacceptable.

The statements made during the Committee hearings 30 and the Senate Report 31 thus establish that subsection 103(c) was designed to help encourage teamwork, but the focus was on teamwork within organizations, for reasons that the legislative history does not fully illuminate. The Federal Circuit relied on this understanding in its 1997 ruling in OddzOn Products, Inc. v. Just Toys, Inc., holding that non-public information under § 102(f) or § 102(g) could be considered as evidence of obviousness under §103(a), provided that the information did not qualify under the limited § 103(c) exception. 32 The issue of collaborative research projects involving individuals employed by different institutions, however, was not directly addressed as a concern.33 Those offering observations on the narrow scope of the 103(c) amendments, however, failed to provide any explanation of why the provision should not extend to research between organizations, provided the same safeguards against multiple patents on obviously related inventions could be provided.

## E. The Irony of OddzOn in Light of the Modern Research Environment

As a result of the Federal Circuit's ruling in OddzOn, collaborative research conducted by researchers at two or more entities may preclude patentability of the resulting inventions if the entities do not assign their rights to a single entity or create a legal structure of "common ownership" of the invention and the "subject matter" in question. Ironically, the Federal Circuit relied on the 1984 amendments to § 103—which was enacted to encourage team research—to reach this result

In OddzOn, the Federal Circuit considered the appeal of a case of patent infringement in which a toy company, OddzOn, sued another company, Just Toys, for creating an obvious variation of a toy based on confidential information that it had shared with Just Toys. The district court held that the confidential information qualified as subject matter within the meaning of § 102(f), and concluded that this information could be combined with other prior art under § 103 to make a deter-

mination of obviousness. On appeal, the Federal Circuit upheld these conclusions.

Judge Lourie, writing for the Court, first noted that the Federal Circuit had never before decided the prior art status under § 103 of subject matter derived by a patent applicant within the meaning of § 102(f).<sup>34</sup> He then examined the construction of

<sup>&</sup>lt;sup>28</sup>Patent Law Improvement Act: Hearing on S. 1535 and S. 1841 Before the Subcomm. On Patents, Copyrights, and Trademarks of the Senate Comm. On the Judiciary, 98th Cong. 18–

<sup>39, 55–81 (1984) (&</sup>quot;Hearing on S. 1535 and S. 1841").

29 Hearing on S. 1535 and S. 1841, 55–81 (Statement of Bernarr R. Pravel, American Intellectual Property Law Association) ("Given that *In re Bass* and *In re Clemens* were the two cases cited here, it appears that the inclusion of subsection 102(f) in the bill was a result of the subsecited here, it appears that the inclusion of subsection 102(f) in the bill was a result of the subsequently overruled reasoning in  $In\ re\ Clemens$ . As discussed above,  $In\ re\ Bass$  clearly stated, in dictum, that subsection 102(f) was not prior art and should not be combined with section 103. However, the confused reasoning of the CCPA in In re Clemens, conflated subsections 102(g) and 102(f) by holding that personal knowledge was required under 102(g) in order for it to be considered as prior art under § 103. As a result, the  $In\ re\ Clemens$  decision was essentially reversed as erroneous dictum by Kimberly-Clark. Nevertheless, the inclusion of subsection 102(f) in the 1984 amendment is a lasting testament to the erroneous reasoning of  $In\ re\ Clemens$ . There is no other explanation for its inclusion there.")  $^{30}$  Hearings Before the Subcomm. On Courts, Civil Liberties, and the Administration of Justice of the Comm. On the Judiciary, House of Representatives, 98th Congress (1984). ["Judiciary Committee Hearings"]; Hearing on S. 1535 and S. 1841.  $^{31}$  Patent Law Amendments of 1984: Senate Report 98–663 to Accompany S. 1535, 98th Cong.  $^{1984}$ ) ["Senate Report 98–663"].  $^{32}$  122 F. 3d at 1403–1404.

<sup>&</sup>lt;sup>32</sup> 122 F. 3d at 1403–1404.

<sup>33</sup> See, e.g., Judiciary Committee Hearings at 6 (Statement of Gerald J. Mossinghoff, Asst. Secretary and Commissioner of Patents and Trademarks).

retary and Commissioner of Fatents and Trademarks).

34 122 F.3d at 1401. The Federal Circuit, in Lamb-Weston, Inc. v. McCain Foods, Ltd., expressly decided not to analyze this issue. 78 F.3d 540, 544 (Fed. Cir. 1996). Judge Newman's dissent, however did analyze the issue and opined that § 102(f) should not be considered within the scope of § 103. *Id.* at 548–550. Judge Newman relied on the precedent set by Bass which stated, in dictum, that § 102(f) has nothing to do with prior art or § 103. *Id.* at 549. The Board of Patent Appeals and Interferences also addressed this issue in 1985, and rendered the same

§ 102 to determine which subsections may be considered provisions that define prior art. He concluded that subsections (a), (b), and (e) all clearly define prior art, as they involved publicly known information. Subsection (g), he stated, defined prior art as it related to prior inventions of others that were either public or would likely become public, reasoning that such inventions, to qualify under 102(g), must have not been abandoned, suppressed, or concealed. He determined that subsections (c) and (d), however, are loss-of-right provisions not related to information and, thus, clearly not prior art. As to section 102(f) information, Judge Lourie noted that courts generally had not included non-public information within the scope of prior art.<sup>35</sup> generally had not included non-public information within the scope of prior art. To For example, he noted that the CCPA, in In Re Bass, had stated, in dictum, that "[o]f course, . . . (f) [has] no relation to \$ 103 and no relevancy to what is 'prior art' under \$ 103," based on the logic that \$ 102(f) does not relate to subject matter that is, or necessarily will become, public. Notwithstanding this observation, Judge Lourie pointed to the language and legislative history of the 1984 amendment to \$ 103(c) to find that it was the intent of Congress that information falling into the definition of \$ 102(f) does qualify as "prior art" under 103, unless otherwise exempted. The court thus held that the language of \$ 103(c) explicitly qualifies information defined in subsection (f) as "prior art" eligible for use in obviousness determination defined in subsection (f) as "prior art" eligible for use in obviousness determinations under 103. In making his decision, Judge Lourie acknowledged that this interpretation runs counter to the purpose of § 103(c) to encourage team research:

There was no clearly apparent purpose in Congress's inclusion of § 102(f) in the amendment other than an attempt to ameliorate the problems of patenting the results of team research.

Judge Lourie noted that this interpretation of the statute was also adopted by the PTO's regulations, which state as follows:

Subject matter which is developed by another person which qualifies as prior art only under 35 U.S.C. 102(f) or (g) may be used as prior art under 35 U.S.C. 103 against a claimed invention [in the absence of common ownership or assignment at the time of invention 1.38

Judge Lourie recognized that the court's holding would overturn long-held views regarding the status of information under section 102(f). He noted, however, that the role of the court in construing the legislative history would be best served by the court providing a "clear" ruling, rather than the most "logical" ruling, stating:

It is sometimes more important that a close question be settled one way or another than which way it is settled. We settle the issue here (subject of course to any later intervention by Congress or review by the Supreme Court), and do so in a manner that best comports with the voice of Congress. Thus, while there is a basis for an opposite conclusion, principally based on the fact that \$102(f) does not refer to public activity, as do the other provisions that clearly define prior art, nonetheless we cannot escape the import of the 1984 amendment. We therefore hold that subject matter derived from another not only is itself unpatentable to the party who derived it under § 102(f), but, when combined with other prior art, may make a resulting obvious invention unpatentable to that party under a combination of §§ 102(f) and 103.<sup>39</sup> (emphasis added)

Despite precedent to the contrary 40 and a legislative objective of encouraging team research, the Federal Circuit interpreted the plain language of the statute to find that information under § 102(f) and § 102(g) may be considered as prior art in § 103 obviousness determinations, where the information did not fall under the narrow exclusion of § 103(c).

### IV. DETRIMENTAL IMPACT OF ODDZON ON RESEARCH COLLABORATION

Under current law and practice, particularly as affirmed by the Federal Circuit in OddzOn, collaborative research efforts face unnecessary and inefficient burdens. The burdens fall disproportionately on the shoulders of universities and public-sector research organizations. Private companies engaging in research collaborations

opinion as the Federal Circuit in OddzOn. See, Ex parte Yoshino and Takasu, 227 U.S.P.Q. 52,

<sup>54 (</sup>P.O. Bd. App. 1985).

35 122 F.3d at 1401–1402, citing *In re Bass*, 474 F.2d 1276, *Kimberly-Clark Corp.* v. *Johnson & Johnson*, 745 F.2d 1437, 1453 ("[prior art is] technology already available to the public.")

36 122 F.3d at 1402, quoting *In re Bass*, 474 F.2d at 1290.

37 122 F. 3d at 1403.

38 37 CFR § 1.104(c)(4).

<sup>&</sup>lt;sup>39</sup> 122 F.3d at 1403.

<sup>&</sup>lt;sup>40</sup>See, e.g., Gambro Lundia v. Baxter Healthcare Corporation, 110 F.3d 1573 (Fed. Cir. 1997).

can maneuver around the threat of an obviousness rejection by crafting elaboratealbeit entirely fictional—entities and arrangements regarding ownership, assignment and licensing of potential rights that may arise under a patent. Even so, such maneuvering—which is done solely to avoid a potential defect in patent rights—is inefficient and counter-productive. Research partnerships that include a public entity or university, however, face more serious problems, particularly in situations where requirements governing public partnerships prevent such legal maneuvers. In both cases, however, unnecessary barriers and complications exist that complicate collaborative research endeavors of any kind. As such, § 103(c), in its current form, serves as an overall deterrent to collaborative research efforts among entities.

Despite the ruling in OddzOn, private companies may be able to avoid obviousness rejections for patents under \$102(f) and \$102(g) by creating an arrangement whereby their joint research satisfies the \$103(c) exception for assignment and common ownership. <sup>41</sup> Section 103(c) states that subsections 102(f) and (g) "shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." Thus, both the patent rights to the future invention and the rights to other shared information derived independently of the joint research, which could be considered prior art under subsections 102(f) and (g), must be assigned to one entity or owned by the same entity.

Private parties may structure their assignment in a number of ways. Although these methods have not been tested in litigation, some seem more certain to satisfy the § 103(c) exception than others. In the case where researchers in each private entity have assigned their patent rights to their respective employer, one of the private entities can then simply assign its patent rights to the other collaborating entity. From a practical business standpoint, however, this may not be the most feasible solution, as it will be difficult to convince one entity to assign both past and future

patent rights to a research partner

Another alternative is for the collaborating private entities to create a shell company or joint venture to which they can both assign their interests. Note that a merger of the two collaborators would also satisfy the common ownership exception. A merger or joint venture would allow for common ownership, and thus would most likely protect patentability of the ultimate invention. With a joint venture, both entities would be able to maintain independent control over their independently developed innovations. The creation of a shell company, however, adds extra costs to the research collaboration.

Yet another alternative is to have the individual researchers in each entity simultaneously assign their patent rights to both entities, thereby creating a situation of common ownership without the need to form a shell company. Whether or not this alternative would qualify under the § 103(c) exception is especially uncertain.

Another possibility for collaborating entities attempting to preserve their individual patent rights is to manipulate the scope of the assignment. For example, the entities may enter into a contract that ensures that the patent rights were assigned to one party "at the time the invention was made," as stated by § 103(c), but they may include a clause in the contract granting the assignor the right to demand that any or all of its assigned rights be returned to it after the invention has been filed with the PTO. Clearly though, such an assignment might well be declared an invalid sham assignment created solely for the purpose of fitting within the scope of the § 103(c) exception. 43 It will be left to the courts to decide the validity of this type of short-term assignment, creating a high level of uncertainty for entities pursuing

# B. Collaborations With Public Entities

Although §103(c) makes it more difficult and more expensive for private researchers to collaborate with one another and still preserve the patentability of the resulting inventions, the addition of a public sector entity into the collaboration can pose insurmountable barriers in some cases. The combination of § 103(c) and the laws

42 See Viginia C. Bennet & Sorojini J. Biswas, Protecting the Patentability of Your Collaborative Research, 15 NATURE BIOTECH 472, 473 (1997).

<sup>&</sup>lt;sup>41</sup> See Steffe, Kraus, and Millonig, at 179–182.

<sup>&</sup>lt;sup>43</sup>The Patent Act recognizes assignments of the whole interest; and the assignments of "any interest therein." 35 U.S.C. § 261. The Supreme Court has declared that the transfer of either of three kinds of interests is an assignment: (1) the whole patent, comprising the exclusive right to make, use, and vend the invention throughout the United States; (2) an undivided part or share of that exclusive right; or (3) the exclusive right under the patent within and throughout a specified part of the United States. Waterman v. Mackenzie, 138 U.S. 252, 255 (1891).

governing public collaborations creates a scenario whereby these partnerships will

often result in unpatentable inventions.

Section 103(c) creates a number of situations in which a collaboration with a public entity may result in an unpatentable invention. The most common situation involves a research partnership between a private and public entity, or between two public entities, in which one or both partners, in the course of conducting research, share innovations with the other that had been developed independent of the collaboration. Even if there is a formal agreement as to which partner will receive ownership of the ultimate invention, information developed outside of the collaboration that is shared between the partners may also be considered prior art for a § 103 obviousness determination. Therefore, to preserve patentability, the rights to this independently derived information must be assigned to the entity that has been assigned the patent rights to the ultimate invention.

For a variety of reasons, not the least of which is law that governs the disposition of patent rights arising from Federally funded research 44 public entities often cannot transfer rights to this independently derived information to their research partners. Similarly, because the potential for such independently derived information is largely unknown, private companies may not be willing to assign their rights to such information to a public entity in order to preserve the patentability of potential inventions arising from the collaboration. Ironically, though, it is exactly this independently derived information that makes a collaboration so desirable.

As detailed in Part II, research collaborations between private corporations and universities are an important form of research partnerships. Universities, however, and especially public universities, are limited in their ability to assign patent rights. To illustrate just one example, the University of California retains all patent rights derived from collaborations:

The University retains all patent rights from sponsored research, and any invention or patentable idea conceived or reduced to practice in the course of the research belongs to the University.45

Hence, under § 103(c), if the research partner contributes any independently derived information qualifying under subsections 102(f) or 102(g), the only way for the University of California to preserve the patentability of an invention resulting from this research collaboration would be to obligate the research partner to assign to the University the rights to all of these independently derived ideas. In contrast to a collaboration between private entities, the option of transferring the rights to this previously derived information to a joint venture does not appear to exist for the University of California. The potential research partner, then, will be left with the choice between relinquishing its rights to independently derived discoveries or avoiding the collaboration with the University. In many cases, due to the potential value of the independent discoveries of the research partner, it will opt for the latter

Federally sponsored research collaborations face similar difficulties. The Stevenson-Wydler Act, as amended by the Federal Technology Transfer Act of 1986, authorizes Federal laboratories to enter into cooperative research and development agreements (CRADA) with private industry, universities, other Federal agencies, State or local government, foundations, nonprofit organizations, or other persons. 46 The Federal laboratory may grant, or agree to grant in advance, patent licenses or assignments in any invention made partially or wholly by a Federal laboratory under the CRADA.<sup>47</sup> The Bayh-Dole Act encourages collaboration in the context of "federally supported research or development," by allowing government contractors the option to retain title to the resulting invention under certain circumstances. 48

www.ucop.edu/ott/brochure.html.

46 15 U.S.C. § 3710a.

47 15 U.S.C. § 3710a(b)(1). In consideration for the Government's contribution under the agree-

4835 U.S.C. § 200. The Bayh-Dole Act originally addressed only nonprofit organizations and small business firms. 35 U.S.C. § 202(a). An Executive Order clarified that Bayh-Dole should not

<sup>44 35</sup> U.S.C. Section 202(c) (7). The Bayh-Dole Act provides, in the case of a nonprofit organization or small business entity, "a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency [that funded the research leading to the invention]."

45 Industry Brochure, University of California, Office of Technology Transfer, http://

nent, assignments or licenses are subject to several explicit conditions. 15 U.S.C. § 3710a(b)(1). Among others,, the Government shall always reserve a "nonexclusive, nontransferable, irrevocable, paid-up license from the collaborating party to the laboratory to practice the invention or have the invention practiced throughout the world by or on behalf of the Government." 15 U.S.C. § 3710a(b)(1)(A).

In the cases where the Federal Government maintains title to the inventions that arise from a joint research project, the results under \$103(c) will be essentially identical to those discussed above regarding a university-corporation partnership where

the university maintains the patent rights.

The more difficult scenario occurs when the research partner under the Bayh-Dole or Stevenson-Wydler Acts is granted title to the ultimate invention, and the government plans to share independently developed information with the research partner. In this case, the barriers to patentability created by \$103(c) may become insurmountable. In order to fit within the \$103(c) exception, the government agency, such as the NIH or NSF, must transfer to the research partner the rights to the independently derived information that it shares during the course of the joint research, if this information could be categorized within subsections 102(f) or 102(g). The political feasibility of such a transfer of federally owned prior art to a research partner is dubious, as there will be a negative public outcry if this information is taken by the research partner to later invent something that is not related to the collaborative research. Again, the protections of joint ventures created by private entities do not appear to be available for partnerships with government entities under these Acts.

The addition of a third partner to a collaboration merely exacerbates the difficulties. When a third partner joins the research collaboration, and where title remains with one of the other two partners, the third partner must also assign the rights to its independently developed innovations to the patent holder of the resulting invention. In partnerships involving public entities where joint ventures are not utilized, the third partner will again have to choose between foregoing the research collaboration or giving up its rights to information of uncertain value which it had developed independent of the collaboration. In many cases, the decision of the poten-

tial third partner will be to forego the collaboration.

The above examples illustrate the substantial complications that arise from the Federal Circuit's interpretation of § 103(c) in *OddzOn*. The tremendous costs that result from application of § 103(c), in the form of deterred research collaborations, lost inventions, and legal fees, are not balanced by any apparent benefits. Section 103(c) must be substantially modified in order to allow all joint researchers to share information without fear that their inventions will be made unpatentable by the very information sharing that makes their collaboration fruitful.

#### V. POSSIBLE CHANGES TO ADDRESS ODDZON

AUTM supports efforts of Congress to legislatively address the problems facing joint researchers who are not located within a single entity, or where they have not

commonly assigned their rights to an invention to a single entity.

One approach may be through revision of the scope of section 103(c) to give formal inter-entity research collaborations a status equivalent to that given to collaborations within a single organization. It would be desirable to treat research collaborations that are typically formed under most university settings the same as collaborations formed within private sector research teams, provided that the same or equivalent safeguards against multiple patents issuing on obviously-related inventions to different entities are included in the legislation.

We believe a narrow exception can be crafted to precisely address this scenario. Such an exception should be available only in situations where a formal relationship was established among the parties or the organizations employing the parties that are sharing the information *prior* to the time the invention was made. The exception can be made contingent on one entity "controlling" use of any patent rights arising out of the joint research. The legislation also should focus on the scenario where the exception will be most relevant; namely, where two individuals communicate information amongst themselves, after which, an invention is developed in which only one of the two is the inventor. If both parties are "inventors" of the later-derived invention, there is no need for special treatment under the law.

It would also be appropriate to limit the exception to the first patent application filed that containing information generated or transferred under the collaboration.

It would also be appropriate to limit the exception to the first patent application filed that containing information generated or transferred under the collaboration. This would prevent the possibility of two patents being granted on closely-related inventions to different entities of a qualifying research collaboration, other than where one of the parties can show that they "invented" the technology prior to the filing date of the first patent. This will be an extremely rare occurrence.

be interpreted to limit the right of agencies to enter into similar government contracting agreements with large businesses. Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy, Pub. Papers 248 (Feb. 18, 1983). This was codified by Congress in 1984. 35 U.S.C. § 210(c).

In a typical collaborative setting, there is a formal understanding between the collaborators as to the disposition of interests regarding any patent rights that arise from the research project. Ordinarily, provisions are included that govern which party will be responsible for filing patent applications on inventions that arise, the handling of such applications, and the use of patent rights.

A rule that makes the exception available only to the first-filed application will

prevent two independent patents arising in the first instance in most circumstances. It will also render the question of 102(e) largely irrelevant (other than with respect to patents owned by parties unrelated to those making up the collaboration). This would also provide a better solution than what is provided under current practice with respect to patents owned by the same entity; namely, the use of non-statutory double patenting grounds (e.g., terminal disclaimers).

Thus, Congress can ably address concerns over expansion of the scope of section 103(c) by incorporating safeguards into the legislation. Congress can craft the law in this manner to create a parallel situation to what exists today for patents that

are commonly owned or assigned.

#### VI. CONCLUSION

The OddzOn decision has introduced a new and undesirable uncertainty into the validity of patents arising out of collaborative research between entities, particularly collaborations with governments and universities. It is ironic that this uncertainty has arisen out of a decision interpreting the 1984 amendments that were designed to encourage team research. The Federal Circuit's interpretation of the law, while accurate, directly conflicts with the purpose of the 1984 amendments, and undercuts the objectives set out in the Stevenson-Wydler and Bayh-Dole Acts. Accordingly, AUTM supports an amendment of section 103(c) to enable the free flow of information among collaborative researchers within or between institutions, without unnecessary concern over the patentability of inventions arising from their team effort.

American Council on Education



March 13, 2002

The Honorable Howard Coble Chairman Subcommittee on Courts, the Internet and Intellectual Property B-351A Rayburn House Office Building Washington, D.C. 20515

Dear Mr. Chairman:

The American Council on Education (ACE) and the National Association of State Universities and Land-Grant Colleges (NASULGC) write to commend you for holding an oversight hearing on "patent law and non-profit research collaboration." Founded in 1918, ACE is this country's coordinating higher-education association, representing 1,800 accredited, degree-granting colleges and universities from all sectors of higher education and education-related organizations. Founded in 1887, NASULGC is the nation's oldest non-profit higher education association, comprised of 213 state universities, land-grant institutions, and historically black universities, with members in every state and U.S. territory.

In the United States, patent law and non-profit research is a measurable success story. According to a survey issued last year by the Association of University Technology Managers, the commercialization of academic research in 1999 resulted in more than \$40 billion in economic activity that supported more than 270,000 jobs. Academic technology transfer – specifically the licensing of innovations by universities, teaching hospitals, and research institutes – has contributed to the creation of major businesses and industries, and has opened new markets. The transfer of technology from institutions of higher learning has contributed to new medical treatments, breakthroughs in electronics, improvements to agriculture, and protections to the environment, among many others.

Legislation enacted in the Patent and Trademark Law Amendments Act of 1980 (the Bayh-Dole Act), and subsequent amendments in 1984, created a uniform patent policy among the many federal agencies that fund research, enabling non-profit organizations (universities paramount among them) to retain title to inventions made under the federally-funded research programs. Prior to 1980, fewer than 250 patents were issued to American universities annually and discoveries were rarely commercialized for the benefit of the public. In comparison, in 1999 annual invention disclosures by universities rose to over 12,000 and patent filings increased to 5,545 (a 77% increase over the preceding year).

The Honorable Howard Coble March 13, 2002 Page 2

During the past two decades, universities have been encouraged to engage in collaborative activities within their respective academic and research communities, and further to collaborate with each other and the private sector. Collaborative research is very much in the public interest because much research is conducted with taxpayers' money, and the costs and complexity of cutting-edge research are growing exponentially.

However, current patent law (in 35 U.S.C. § 103(c)) contains a serious threat to collaborative research. Current law, as construed by the U.S. Court of Appeals for the Federal Circuit (*Oddzon Products, Inc. v. Just Toys, Inc.*, 122 F. 3d 1396 (Fed. Cir. 1997)) provides that prior art, under two provisions in the Patent Act (section 102(f) and (g)), could be used to determine the obviousness of an invention in situations where (1) there was no common ownership or assignment of the invention and information being shared among the collaborations, and (2) the exchanged information was not publicly known.

This threat is not what this Subcommittee, under the then-leadership of Representative Robert W. Kastenmeier and Carlos Moorhead, intended when section 103(c) was amended by the Patent Law Amendments Act of 1984 to encourage open communications among research teams working in universities, corporations and other organizations. The legislative intent of the 1984 amendment, narrowed dramatically by the Federal Circuit's decision, should be restored in the statutory text.

ACE and NASULGC therefore support an amendment to the Patent Act to promote collaborative research amongst the university and non-profit sector, the private sector and government to achieve the spirit of the 1984 amendment. We urge you to draft, introduce and process through the House clarifying legislation in the very near future. We are grateful to you for recognizing the importance of patent law and non-profit research collaboration and the significant contributions that universities and colleges make to the welfare and economy of our country, and we look forward to working with you to effectuate the policy goals identified in your oversight hearing.

Sincerely,

Responsibility Steinbach

SES/cms

c: The Honorable Howard Berman Blaine Merritt Chris Katopis Alec French Maureen Mellody

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